3vAALuation

Manual of measuring instruments for the evaluation of AAL solutions

AUSTRIAN INSTITUTE OF TECHNOLOGY

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Abstract

The research and development of age-appropriate assistance systems for a self-determined life have become much more important in recent years. This is due to demographic developments which are characterized, for example, by a strong increase in the proportion of people over the age of 65 in the population and by increasing urbanization. In this context, Ambient or Active Assisted Living (AAL) products and services are intended to contribute to the increase or maintenance of the quality of life of older and aging people so that they can lead an autonomous and self-determined life for as long as possible.

The application areas of AAL are diverse and range, for example, from health, care, housing, buildings, mobility, or transport to work as well as leisure and culture. There is primary (e.g. end users), secondary (e.g. care and support organizations), and tertiary interest (e.g. political decision-makers) in the comprehensive implementation of AAL. To date, however, such solutions have not yet been established in everyday life or are still in the test phase. For this purpose, scientifically substantiated evaluation results are needed that show whether AAL solutions have an additional value and what concrete additional value they have, as well as appropriate valid and reliable data collection approaches. However, AAL-specific measuring instruments that address the specifics of the target group and technologies are not yet available. There is also no uniform understanding regarding the constructs to be measured, which makes it difficult to compare results.

Against this background, the studies “EvAALuation² - Development of measuring instruments for the proof of the effectiveness of AAL solutions”, funded within the “benefit” program, and “3vAALuation - Development of Standardized Measuring Instruments for the Assessment of AAL Technologies” pursued the objective of developing concrete instruments for the evaluation of the effects and effectiveness of AAL solutions and thus build on the preliminary project “EvAALuation”. As regards content, the focus is on the application areas of health, care & support as well as being active & human potential. These fields of the application make it possible to demonstrate the versatility of AAL solutions and allow a concrete operationalization for the measurement of effects and efficiency enhancement. The developed instruments are characterized by a multi-perspective approach as well as high practicability to motivate the application. The measuring instruments were generated through an iterative process which included a workshop with relevant stakeholders, expert interviews, and qualitative as well as quantitative pre-tests for validation and reliability examination.

The result exists in the form of this manual in which relevant measurement instructions for the evaluation of AAL solutions are described. These iteratively developed and validated measuring instruments are divided into reactive data collection through questionnaires and non-reactive methods that describe detailed instructions for the collection of relevant key figures. The reactive method descriptions contain, among other things, instructions on the use of questionnaires and the avoidance of process errors, instructions for test persons on how to answer questions and evaluation notes, while non-reactive measurement instructions describe relevant data sources, measurement objects, measurement times, and measurement modes. Furthermore, we highlight national differences and draw attention to methodological implications of cross-national studies.

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Preface

This handbook was developed within the framework of the R&D service "EvAALuation[2] - Development of measuring instruments for the proof of the effectiveness of AAL solutions", commissioned as part of "ICT of the Future: benefit – Opportunity through Demographic Change" by the Austrian Research Promotion Agency (FFG) and the Federal Ministry for Climate Action, Environment, Energy, Mobility, Innovation and Technology (BMK, formally known as BMVIT) as well as the directly commissioned project "3vAALuation – Development of standardized measuring instruments for the assessment of AAL technologies" funded by the Austrian Research Promotion Agency (FFG) and Federal Ministry for Climate Action, Environment, Energy, Mobility, Innovation, and Technology (BMK).

The aim of the study conducted by the Center for Technology Experience of the AIT Austrian Institute of Technology and the Institute for Applied Research on Ageing (IARA) of the Carinthia University of Applied Sciences (CUAS) was to further develop EvAALuation based on the indicator set also commissioned within the "benefit" program. In EvAALuation, the AIT Austrian Institute of Technology, the Carinthia University of Applied Sciences, and Solgenium developed a comprehensive set of indicators to record the effects of AAL technologies on a subjective, institutional and social level. The set shows which indicators can be used to operationalize vitality and quality of life goals, social goals, social system goals, economic and innovation goals as well as design and technology goals. In EvAALuation² and 3vAALuation, concrete measuring instruments for the evaluation of AAL solutions have now been developed, focusing on three concrete application areas - health, care & support, and being active & human potential. These application examples show the versatility of AAL products and services and allow concrete operationalization proposals at the same time. The developed instruments are characterized by a multi-perspective approach, i.e. the inclusion of subjective, institutional, and societal levels, and practicability through precise application instructions in order to motivate the use in practice and to enable comparability of the assessment of AAL products and services. This handbook is aimed at all persons involved in the evaluation of AAL systems. Accordingly, the presentation strives to be understandable also for those who do not have expertise in the field of methodology, but nevertheless to provide all relevant subject-specific information. In particular, the application examples are intended to make it easier for interested parties without in-depth knowledge to understand the possible uses of the instruments.

Compliance with qualitative standards of the developed questionnaires and survey instructions took place in the form of an iterative procedure and through the inclusion of AAL users, experts and stakeholders, whom we would like to thank at this point for their time, cooperation, and valuable advice. Furthermore, we would like to thank Dr.in Gerda Geyer, Dipl.-Phys. in Kerstin Zimmermann and Mag.a Verena Mussinig for their support in the context of the implementation of the project.

The results of the **EvAALuation** study can be accessed here: https://www.ffg.at/sites/default/files/allgemeine_downloads/thematische%20programme/IKT/evaaluation_handbuch_final.pdf

The results of the **EvAALuation²** study can be accessed here: https://www.ffg.at/sites/default/files/allgemeine_downloads/thematische%20programme/Energie/EvAALuation2_D4.2_Handbuch_final.pdf

Introduction

Interest in the practical and comprehensive implementation of Ambient Assisted Living (AAL) products and services is manifold. However, the additional value of these solutions has not yet been sufficiently empirically verified, and measuring instruments specifically developed for the evaluation of AAL systems are not yet available. In detail, there is a lack of instruments that are both appropriately designed for the user group of older people ("target-population appropriate" instruments) and that can record AAL-specific measurement goals ("intervention-adapted" instruments). Furthermore, the existing instruments do not take into account the specifics resulting from the experimental and/or trial introduction of assistive technologies ("process-adapted" instruments). Concerning the temporal component, appropriate evaluation processes in their simplest form can be subdivided into the following process elements: resource input (e.g. costs for the development of AAL solutions), implementation, outcome, i.e. direct results generated by the implementation (e.g. improvement in quality of life) and effects, i.e. indirect changes resulting from the implementation (e.g. potential savings in the publicly financed health care system). Accordingly, relevant data for the evaluation of AAL solutions are to be collected at the appropriate point in time; a subsequent determination of relevant indicators is in many cases only conditionally or not possible. The process elements mentioned do not usually run linearly and it is necessary to take possible feedback processes into account (Kellog Foundation 2001). In concrete terms, this means that, for example, improvements of the solutions are subsequently made based on newly gained knowledge during the implementation of AAL solutions.

The research projects EvAALuation[2] and 3vAALuation, carried out by the Center for Technology Experience of the AIT Austrian Institute of Technology and the Institute for Applied Research on Ageing (IARA) of the Carinthia University of Applied Sciences, thus aimed at supporting evaluations by including subjective, institutional and societal perspectives through the provision of practicable measuring instruments. The main focus was on the application areas of health, care & support as well as being active & human potential.

The study "EvAALuation - Development of a set of indicators for the measurement of effects and efficiency enhancements of AAL solutions" (Himmelsbach et al. 2017), funded by the Austrian Research Promotion Agency (FFG) and the Federal Ministry for Climate Action, Environment, Energy, Mobility, Innovation and Technology (BMK, formally known as BMVIT) as part of the "benefit" program, served as the basis. The process of developing the scientific solution approach follows the total survey error approach. This approach primarily considers possible sources of error in data collection and resulting quality standards, in particular objectivity, reliability, validity, and practicability. Validity was ensured mainly through expert interviews and a cognitive pre-test with the target group. After a new iteration of the measuring instruments, evidence on the interpretation of the measured values, especially the reliability of these interpretations, was generated in a quantitative pre-test through questionnaires and experimental surveys. These insights are also incorporated into the process description and thus ensure objectivity through standardization.

The results of the **EvAALuation** study can be accessed here*:* https://www.ffg.at/sites/default/files/allgemeine_downloads/thematische%20programme/IKT/evaaluation_handbuch_final.pdf

As a result, operationalization proposals are now available for the above-mentioned areas of application. In detail, operationalizations of the indicators from EvAALuation, which include vitality & quality of life goals, social goals, social system goals, economic & innovation goals as well as design & technology goals of AAL solutions (Himmelsbach et al. 2017), were developed for the areas of health, care & support and being active & human potential. For reactive data collection, a questionnaire was developed in each case. For non-reactive data collection, detailed instructions for the collection of key figures were provided.

The results of the **EvAALuation²** study can be accessed here: https://www.ffg.at/sites/default/files/allgemeine_downloads/thematische%20programme/Energie/EvAALuation2_D4.2_Handbuch_final.pdf

In 3vAALuation, the EvAALuation² results were then adapted for international studies: This includes the translation of the manual, translation and review of the English questionnaires, and adaptation and extension of the non-reactive instruments concerning selected regions as well as cross-national evaluations. To support future practical application, the results were presented in a handbook and illustrated by means of three case studies.
Accordingly, the handbook is structured as follows: Part A provides insights into the methodology and the individual steps for developing the instruments to ensure transparency and traceability. Part B presents both the reactive instruments, i.e. the questionnaires, and the non-reactive instruments, i.e. the instructions for collecting key figures. Finally, Part C illustrates the possible use of these instruments in cross-national evaluations.

PART A – Description of the Method Development Process

Part A provides an insight into how the final measuring instruments of this handbook were developed within the framework of the EvAALuation[2] and 3vAAluation studies. In the following, a brief outline of the methodology and the basic principles of the approach as well as insights into various interim results are presented.

1. *Objective*

EvAALuation[2] aims to operationalize the comprehensive findings of the preliminary project EvAALuation. The overarching goal is to transfer the indicator set for determining the effects and efficiency enhancements of AAL solutions into evaluation practice. For this purpose, the set of indicators already developed will be expanded, on the one hand, by a temporal component in the context of the development and implementation of AAL solutions. On the other hand, it is necessary to develop a uniform evaluation standard for age-appropriate assisting systems, which will enable comparability between AAL solutions in the future first place. In so doing, concrete measuring instruments, including reactive and non-reactive data collection procedures for the evaluation of AAL solutions on a subjective, institutional and societal level, will be developed on the basis of the EvAALuation indicator set.

Reactive data collection procedures are characterized by the fact that data are obtained as a reaction to a research action, e.g. interviews, while non-reactive procedures use, process-produced data or behavioral traces, for instance, and thus avoid specific behavioral effects, such as interviewer effects (Diaz-Bone & Weischer 2015). 3vAALuation gives recommendations on the choice of survey procedures, whereby concrete survey instructions were developed in the area of non-reactive procedures and concrete question and answer items for standardized surveys in the area of reactive data. In addition, instructions on how to use the instruments, notes on how to avoid process errors, and data evaluation and interpretation notes are available.

In EvAALuation[2] and 3vAALuation, the research results from EvAALuation, where potential indicators for the evaluation of AAL solutions had been developed (Himmelsbach et al. 2017), were operationalized (see Fig. 1).

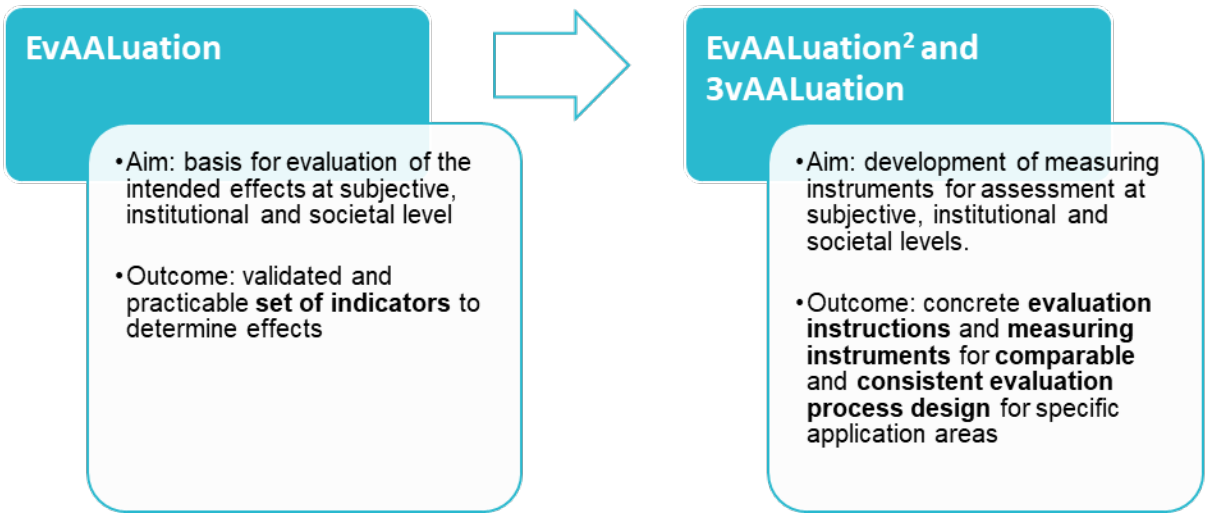


Figure 1: Classification of EvAALuation2 and 3vAALuation within a logical model

In EvAALuation² and 3vAALuation, the operationalization of an indicator was performed by means of the work step that includes making theoretical relationships measurable in practice through appropriate measurement tools. The operationalization of an indicator consists in specifying how the issues it describes can be measured (Schnell et al. 1999). For example, body height can be operationalized by the instruction "measurement by means of a metrestick", whereby the "metrestick" represents the necessary measuring instrument (Meyer 2004). The operationalization of the indicator set thus contains instructions for relevant indicator surveys as well as associated measuring instruments.

In this regard, it should be emphasized that the focus was on specific areas of application within the framework of the project. On the one hand, this is due to the fact that not all indicators are relevant for each AAL product. On the other hand, the definition and the survey method of an indicator also differ depending on the area of application (e.g. contacts to mobile services, 24-hour care). Under the premise of developing practical instruments, the focus should therefore be placed on a selection of application areas. The selection of application areas thereby followed the requirement to include the range of AAL solutions without neglecting AAL-specific core areas. Based on the analysis of AAL tender texts (Himmelsbach et al. 2017), health as well as care & support could be identified as core areas. The relevance of the selection of these application areas is also strengthened by the further increase in healthcare expenditure as a result of the aging population and new diagnosis and therapy methods (OECD 2016). In addition, the area of application "being active & human potential" was selected because, on the one hand, it reflects versatile images of age(ing), also beyond deficit orientations and a focus on physical aspects of age(ing), and explicitly takes into account a need for inclusion and, on the other hand, is of increasing economic relevance.

2. Overview and Research Principles

The process of developing the scientific solution approach followed the total survey error approach, which addresses in particular possible sources of error in data collection and the resulting quality standards (Faulbaum 2014). This is supposed to ensure the implementation of central quality criteria such as objectivity, reliability, validity, and practicability.Table 1 provides an overview of the quality criteria that constituted the focus of interest in the respective work step:

Table 1: Work steps and quality criteria in EvAALuation[2]

Work step	Quality criteria
Indicator selection & operational definition	✓ Relevance, simplicity, comparability
Validation workshop	✓ Completeness, relevance, practicability
Revision and definition of the survey process	✓ Relevance, practicability, validity
Expert interviews and cognitive pre-testing	✓ Validity, relevance
Revision	✓ Completeness, clarity, relevance, validity
Expert interviews and trial tests and quantitative pre-test of reactive data	✓ Practicability, validity, reliability
Revision and process description	✓ Minimization of process errors, objectivity through standardization
Application examples and handbook	✓ Practicability, transparency

In the first step, the indicators for the respective areas of application were selected and a definition was developed, which guided the further operationalization. On the basis of a validation workshop with representatives of the stakeholder groups, these results were reviewed and revised in order to subsequently determine for which indicators a reactive or non-reactive survey was suitable. The development of the concrete instruments followed an iterative approach. Expert interviews and pre-tests contributed to quality assurance and the avoidance of systematic measurement errors. In addition, based on these findings, precise instructions for the application of the measuring instrument and the interpretation of the data were developed. In this way, objectivity was addressed through standardization.

As already mentioned above, the validity of a measuring instrument is one of the central quality criteria that enables statements about the extent of validity of the construct to be measured. Validity was ensured primarily through expert interviews and cognitive pre-tests. In the development process, it was precisely documented how the measuring instrument is to be used and, above all, how the collected data can be interpreted. This step will be clarified in the description of the case studies.

In addition to the validity of the measuring instrument, reliability must also be ensured, i.e. results must be reliably and steadily reproducible in repeated measurements. A number of

different methods are available for this purpose, whereby the selection is naturally oriented towards the structure and characteristics of the features to be examined. A reliability test of the reactive instruments was carried out by means of factor analysis. Furthermore, Cronbach's alpha was calculated to check the internal consistency of item groups (Himme 2007).

Building on EvAALuation[2], 3vAALuation aimed to internationalize the results. This process consisted of three steps shown in Table 2.

Table 2: Work steps in 3vAALuation

Work step
Translation of the existing content
Translation of the manual & quality assurance
Bilingual adaption
Reactive tools: Measurement interpretation evidence and revision Non-reactive instruments: Identification and highlighting of national differences
Expansion of non-reactive instruments to four nations
Characteristics of the medical and care system Characteristics of the share of informal care, acquisition rate, and volunteer hours Pretest of the non-reactive indicators

As a first step, we translated the existing EvAALuation[2] manual. This is followed by a quality assurance by the project team. For the reactive instruments, the items are back-translated in order to identify and correct any deviations from the initial content. The next step was bilingual adaptation. Here, different methodological approaches have to be chosen for the reactive and non-reactive instruments, similar to the procedure in EvAALuation[2]. We report methodological details in the following sections describing the iterative development of the reactive and non-reactive instruments.

Methodically and methodologically, EvAALuation[2] and 3vAALuation are therefore characterized by the reference to the total survey approach, which makes it possible to ensure central quality criteria such as objectivity, reliability, validity, and practicability. For this purpose, stakeholders were involved in several validation loops, and data were collected (on a trial basis) for the purposes of process optimization and the generation of measurement interpretation evidence. Furthermore, the case study method supports practicability. The transparency of method generation is ensured by the preparation in the form of a handbook.

3. Selection of Indicators and Elaboration of Operational Definitions

The first essential step in the development of the measuring instrument was the selection of the indicators to be operationalized for the areas of application. First of all, literature-based definitions were formulated for the respective application areas. After revision based on the feedback from the stakeholders, the following definitions were created:

Health: This area of application includes products and services that determine the state of physical, mental, and social well-being and contribute to its maintenance and restoration. The focus here is on the measurement of body and vital data, diagnosis, disease prevention, and treatment of diseases (based on WHO 2014 and Leitner et al. 2015).

Care & Support: This area of application includes products and services that support and promote the autonomy of individuals who, over a longer period of time, require assistance to perform basic daily activities due to their age, disability, illness, or impairment. This also includes such products and services that are granted to the person or for the person who provides such assistance (based on European Commission 2016, quoted from Ministry of Social Affairs 2016).

Being active & Human Potential: The field of application includes products and services that promote paid and unpaid activity and bring the activity environment in line with personal needs. These activities contribute to lifelong learning, social inclusion, and self-fulfillment in the form of meaningful activities and enable older people to design and develop (based on Stirn 1980 and Leitner et al. 2015).

In the next step, the indicators relevant for the application areas were identified on the basis of the TAALXONOMY references in the EvAALuation set of indicators.

The TAALXONOMY can be accessed here: https://www.ffg.at/sites/default/files/allgemeine_downloads/thematische%20programme/IKT/benefit_846232_taalxonomy_-_studienbericht_apffentlich.pdf

In addition, an initial assessment was made of which variables can be used to make the constructs empirically tangible. In particular, the relevance, the applicability with regard to temporal framework conditions as well as the survey at micro or meso level, the simplicity of the indicators, and the comparability were taken into account. For the selected indicators, extensive literature research was carried out afterward. For this purpose, it was worked out in detail what is to be understood by the respective main indicators (e.g. autonomy and self-determination, life satisfaction) in the context of AAL or the specific areas of application. On the basis of literature and the foundations laid in the context of EvAALuation, a conceptual precision in the form of a nominal definition was developed. This ensures that there is a basic understanding of the meaning of the main indicators (Stein 2014). It was also determined which directly observable variables or (sub)indicators can be used to measure the constructs.

The operational definitions of the main indicators, i.e. the definition of what is specifically understood by an indicator with regard to the empirical survey in the AAL context and which specific aspects are to be measured, were considered particularly critical as they form the basis for all subsequent steps. Therefore, they were validated with stakeholders. The selection of stakeholders is based on the stakeholder groups defined in EvAALuation. Accordingly, representatives from the subgroups public, business, end-user, end-user organizations, and research, i.e. representatives of, for example, research funding agencies, political decision-makers, older people as well as organizations, social insurance providers, scientists, or software developers were invited to a half-day validation workshop.
First, the definitions of the application areas were discussed with regard to their transparency. The selection of indicators and the operational definitions were evaluated regarding their gaps and necessary extensions and relevance, first per application area and then in comparison. In addition, the quality criterion of practicability was also taken into account. This criterion plays a role, especially because the instruments developed are not only to be used by people who are experts in the field of analysis and evaluation within the framework of research projects, but also by various stakeholders who are involved in the research process. Practicability must therefore be taken into account with regard to the instruments, but also with regard to the time of the survey and the stakeholders involved.

Based on the results of the validation workshop, the included indicators were extended and initial definitions were revised or extended. Subsequently, the determination of the survey process took place, i.e. it was determined whether reactive or non-reactive data would be used for the survey of the respective construct and which survey modes (methods) would be expedient.

4. Iterative Development of Reactive Instruments

The English items were developed based on German EvAALuation[2] items. Details of the process and results of the item analysis can be found in the respective manual.[1] Like the German items, the English items conform to the following defined rules (Atteslander 2006):

(1) The items record effects indirectly, i.e. they measure the status quo in order to be suitable for pre-post comparisons, analyses of changes over time, and for experimental designs with control groups.
(2) The target population consists of older people who are addressed by AAL solutions and whose (a) health, (b) care and support situation, or (c) being active is to be supported ("primary users").
(3) For the response items, five-point Likert scales are preferred in order to provide a medium form of response (neutral or "neither"). Therefore, the options "no opinion" or "I don't know" can be omitted, since respondents can use these forms as a neutral escape category if they cannot or do not want to answer questions.
(4) Verbalised scales, i.e. naming all scale points, are preferred to naming only the end points.
(5) In accordance with the preferred use of Likert scales, "I" phrases are used for the items if possible.

German items were generated by two researchers, reviewed by a third researcher, iterated in a cognitive pre-test with two older adults, and revised. Next, a quantitative pre-test was conducted to generate empirical evidence for the quality of the measuring instruments and their potential for generalizing interpretations or general measurement interpretation evidence. Three items were removed from the questionnaires due to insufficient characteristic values.
As a next step, a professional translator translated the items to English. An independent person not familiar with the EvAALuation project series translated the items back to German to ensure the accuracy of the translation. The research team reviewed all variations in the translations and classified them into (a) word order variations, (b) synonyms, and (c) content statement variations. If there were any ambiguities, we consulted with the professional translator. Discrepancies in content statements have been corrected and discussed again by the project team.
Finally, the English items were again pre-tested. In detail, evidence on construct-related interpretation was gathered through a review of the dimensional structure by means of principal component analysis as well as evidence on reliability through a review of internal consistency by means of Cronbach's alpha and item-total correlations. The analysis of the data and the revision of the questionnaires followed the requirement to keep the instruments as similar as

[1] See: Himmelsbach, J., Gerdenitsch, C., Schwarz, S., Neureiter, K., Garschall, M., Aigner-Walder, B., Luger, A., Ofner, R., Oberzaucher, J. (2019). *EvAALuation2. Handbuch für Messinstrumente zur Bewertung von AAL Lösungen*. Wien, Villach. Retrieved from https://www.ffg.at/sites/default/files/allgemeine_downloads/thematische programme/Energie/EvAALuation2_D4.2_Handbuch_final.pdf

possible across the application areas, thus also allowing comparative analyses. This was largely successful for subscales relevant for all application areas; only the vitality and QoL domain shows larger differences in dimensionality.
The questionnaire on health was tested with 228 persons, the questionnaires on care & support with 79 persons, and on being active & human potential with 175 persons.
The quantitative pre-test showed an average processing time of 11 minutes and 30 seconds (*SD* = 07:05) for the questionnaire on health, 15 minutes and 49 seconds (*SD* = 10:36) for the questionnaire on care & support and 11 minutes and 07 seconds (*SD* = 11:37) for the questionnaire on being active & human potential.

4.1. Item Analysis: Item Parameters and Quality Criteria for the Questionnaire on Health

Within the online study, which was conducted using Respondi (respondi.com), data were collected from 228 English native speakers living in the United Kingdom with the native language of English. Participation in the study was voluntary. For this sample, reading glasses and digital calendars were given as examples of assistive devices and technology in the formulation of the items.
The sample consisted of 117 female persons, 110 male persons, and 1 non-binary person with a mean age of 69.84 years (*SD* = 6.26). All but one respondent (99.56%) stated that they use smartphones, computers, PCs, or similar devices on a daily basis; one person uses such devices on a monthly basis.
Item parameters were calculated on the basis of this sample and are presented in the following table. Specifically, mean values, standard deviations, and item-total correlations are shown here and the reliability (Cronbach's alpha) for the scales is specified. One item (AOH4 “I am willing to make use of health services”) has been removed due to low reliability. The reliability values of the final item set range from 0.334 to 0.887 for item-total correlations and 0.560 to 0.994 for Cronbach's alpha.

Table 3: Mean values, standard deviations, item-total correlation, and Cronbach's alpha of the items of the instrument for the evaluation of AAL technologies in the area of health

Item	M	SD	Item-total correlation	Cronbach's Alpha
Access & offer healthcare				.560
AOH1	3.20	1.31	.411	
AOH5	4.15	0.94	.411	
Affordability of healthcare				.701
AH2	3.04	1.12	.541	
AH3	2.75	1.17	.541	
Age(ing)-related self-image				.664
ARSI1	3.77	.953	.519	
ARSI2	3.68	1.078	.607	
ARSI3	2.75	1.171	.334	
Autonomy & self-determination				.839
AS1	4.65	.650	.645	
AS2	4.70	.594	.775	
AS3	4.69	.582	.694	
Freedom of choice regarding service access				.936
FC1	4.76	.536	.887	
FC2	4.78	.474	.887	
Health-promoting behavior				.711
HPB1	3.72	1.119	.512	
HPB2	4.11	1.127	.533	
HPB3	4.15	.779	.594	
Hedonic user experience				.901
HUX2	2.93	1.17	0.82	
HUX3	2.99	1.18	0.82	
Life satisfaction				.944
LS1	3.84	1.09	.808	
LS2	3.78	1.07	.827	
LS3	4.00	1.02	.811	
LS4	3.55	1.20	.833	
LS5	3.64	1.22	.771	
LS6	3.62	1.10	.791	
LS7	2.96	1.26	.767	
LS8	3.67	1.08	.640	
LS9	3.13	1.28	.804	
Perception of safety				.835
PS1	3.93	1.000	.637	
PS3	3.81	.928	.735	
PS4	3.89	.911	.723	
Pragmatic user experience				.784
PUX1	4.54	0.77	0.43	
PUX4	4.00	1.24	0.74	
PUX5	4.20	1.23	0.79	

Item	M	SD	Item-total correlation	Cronbach's Alpha
Privacy				.843
PR1	1.57	.860	.705	
PR2	1.50	.816	.746	
PR3	1.76	.919	.678	
Social interaction				.907
SI1	3.78	1.148	.808	
SI2	3.79	1.162	.834	
SI3	3.81	1.147	.804	
Social participation				.874
SP1	3.60	1.104	.770	
SP2	3.55	1.322	.758	
SP3	3.57	1.216	.759	
Stigma-free design				.832
SFD1	2.01	1.080	.708	
SFD3	2.02	.973	.671	
SFD4	1.34	.681	.579	
SFD5	1.82	.935	.722	
SFD6	1.49	.805	.550	
SFD7	2.41	1.316	.513	
Subjective state of health				.836
SSH1	3.54	1.080	.634	
SSH2	4.25	.936	.719	
SSH3	4.07	.984	.749	
Subjectively relevant activity level				.911
SRA1	4.34	.987	.754	
SRA2	4.63	.718	.679	
SRA3	4.25	1.081	.794	
SRA4	4.38	.970	.702	
SRA5	4.64	.716	.720	
SRA6	4.26	1.074	.662	
SRA7	4.35	.980	.678	
SRA8	4.64	.690	.696	
SRA9	4.26	1.090	.661	
Therapy adherence/-compli-ance				.822
TAC1	4.15	.870	.699	
TAC2	3.97	.922	.699	

Dimensionality of the instrument

Furthermore, a principal component analysis was calculated for each area, i.e. the vitality & quality of life, social aspects, social system, and design & technology, if subscales included more than one item with the same rating system. Kaiser-Meyer-Olkin (KMO) and Bartlett's test of sphericity showed that the assumptions for a PCA are met.

For vitality & QoL, seven components have been identified, presented in Table 4.

Table 4: Rotated component loadings of "Vitality and Quality of Life" for the area of health (item loadings highlighted in gray)

	Life satisfaction	Subjectively relevant activity level	Autonomy & self-determination	Subjective state of health	Perception of safety	Age(ing)-related self-image	Health-promoting behavior
SRA1	.144	.763	.086	.159	.167	.133	.104
SRA2	.207	.664	.373	-.130	.250	.081	.028
SRA3	.186	.735	.228	.256	.121	.156	.026
SRA4	.185	.679	.044	.128	-.104	.505	.122
SRA5	.162	.682	.393	-.141	.143	.297	-.022
SRA6	.144	.635	.009	.313	-.063	.489	.014
SRA7	.172	.694	.162	.269	.062	-.176	.211
SRA8	.257	.670	.449	-.070	.150	-.054	-.028
SRA9	.152	.639	.195	.425	.147	-.187	.180
AS1	.111	.276	.703	.085	.110	-.040	.291
AS2	.206	.270	.805	.132	.118	.073	.030
AS3	.235	.221	.708	.127	.074	.215	.096
SSH1	.341	.206	.234	.713	.237	.223	.039
SSH2	.425	.179	.582	.259	.161	.068	.130
SSH3	.578	.281	.390	.315	.136	.075	.047
LS1	.816	.183	.201	.129	.128	.180	.135
LS2	.851	.208	.187	.145	.107	.078	.149
LS3	.793	.203	.260	.123	.129	.178	.129
LS4	.547	.285	.095	.578	.230	.150	.167
LS5	.473	.249	.128	.628	.201	.247	.047
ARSI1	.178	.058	.075	.153	.215	.673	.195
ARSI2	.297	.172	.195	.162	.316	.649	.145
ARSI3	.434	.040	.010	.098	.591	-.016	.046
LS6	.685	.150	.240	.233	.314	.065	.184
LS7	.651	.114	.024	.314	.400	.054	.150
LS8	.597	.189	.131	.100	.192	.171	.158
LS9	.490	.182	.159	.595	.283	.226	.123
PS1	.400	.354	.089	.164	.505	.141	.072
PS3	.286	.171	.214	.298	.648	.256	.074
PS4	.174	.170	.246	.138	.755	.208	.149
HPB1	.220	.038	.289	.384	.156	.132	.555
HPB2	.128	.065	.056	.049	.078	.043	.838
HPB3	.250	.150	.133	-.016	.061	.205	.741

Based on the PCA, life satisfaction (LS1-5) and self-esteem (LS6-9) are no longer two separate dimensions but self-esteem is part of the life satisfaction subscale. Thus, we identified seven components: Life satisfaction (including self-esteem), subjectively relevant activities, autonomy, subjective state of health, perception of safety, age(ing)-related self-image, and health-promoting behavior. It must be noted that several cross-loadings occurred. However, these

cross-loadings are in line with the definitions of the indicators, but we recommend calculating intercorrelations of the respective scales.

The PCA of the social aspects confirmed the dimensionality of the instrument, as shown in Table 5. Three components have been identified: Social participation, freedom of choice regarding service access, and social interaction.

Table 5: Rotated component loadings of "Social Aspects" for the area of health (item loadings highlighted in gray)

	Social participation	**Freedom of choice regarding service access**	**Social interaction**
SP1	.714	.052	.519
SP2	.873	.049	.299
SP3	.805	-.003	.389
SI_2	.419	.058	.850
SI_3	.488	.028	.788
FC1	.020	.970	.043
FC2	.038	.971	.026

The PCA of the social systems items is presented in Table 6.

Table 6: Rotated component loadings of "Social System" for the area of health (item loadings highlighted in gray)

	Therapy adherence/ compliance	**Affordability of healthcare**	**Access & offer healthcare**
AOH1	.112	.313	.757
AH2	.050	.905	.031
AH3	-.141	.806	.284
AOH5	.227	.017	.842
TAC1	.898	-.066	.178
TAC2	.909	.000	.149

The PCA reveals an additional component: Two items (AH2, AH3) of access & offer healthcare form a separate component with low cross-loadings named affordability of healthcare. Hence, we identified three components: Therapy adherence/-compliance, affordability of healthcare, and access & offer healthcare.

Finally, the PCA of the items operationalizing the design & technology aspects are presented in Table 7.

Table 7: Rotated component loadings of "Design & Technology" for the area of health (item loadings highlighted in gray)

	Stigma-free design	Pragmatic user experience	Privacy	Hedonic user experience
PUX1	-.251	.648	-.052	.065
HUX1	-.003	.145	.011	.929
HUX2	-.073	.216	.036	.921
PUX4	.139	.808	.003	.294
PUX5	.009	.869	.030	.189
SFD1	.838	.014	.062	-.152
SFD3	.795	-.075	.065	-.127
SFD4	.599	-.532	.055	.038
SFD5	.788	-.266	.112	.000
SFD6	.583	-.523	.018	.117
SFD7	.720	.179	.056	.145
PR1	.064	.019	.873	-.052
PR2	.084	.000	.890	-.028
PR3	.086	-.060	.846	.132

Initially, only one subscale operationalized user experience (PUX1, PUX5, HUX1, HUX2). However, the PCA shows that hedonic and pragmatic user experiences have to be separated. In sum, four components have been identified: stigma-free design, pragmatic user experience, privacy, and hedonic user experience. While the other components give a very clear structure, stigma-free design (SFD1-7) shows interesting cross-loadings with the pragmatic UX. Especially in comparison to the other application domains and the differing cross-loading to them, this is an interesting indication of future research questions that can be further explored in empirical studies.

Descriptive statistics (standardization)

The mean values and standard deviations of the scales can be found in the following table. The intercorrelations of the scales can be found in Table 9.

Table 8: Descriptive statistics for the scales of the instrument for the evaluation of AAL technologies in the area of health (the standard deviations of skewness and kurtosis are given in parentheses)

Scale	M	SD	Min	Max	Skewness	Kurtosis
Access & offer healthcare	3.67	0.95	1.00	5.00	-0.402 (0.161)	-0.309 (0.321)
Affordability of health care	2.90	1.00	1.00	5.00	-0.007 (0.161)	-0.41 (0.321)
Age(ing)-related self-image	3.40	0.83	1.33	5.00	-0.15 (0.161)	-0.453 (0.321)
Autonomy & self-determination	4.68	0.53	2.33	5.00	-1.757 (0.161)	3.028 (0.321)
Freedom of choice regarding service access	4.77	0.49	2.50	5.00	-2.17 (0.161)	4.306 (0.321)
Health-promoting behavior	3.99	0.81	1.00	5.00	-0.713 (0.161)	0.06 (0.321)
Hedonic user experience	2.96	1.12	1.00	5.00	0.039 (0.161)	-0.355 (0.321)
Life satisfaction	3.76	0.98	1.00	5.00	-0.724 (0.161)	-0.148 (0.321)
Perception of safety	3.88	0.82	1.33	5.00	-0.525 (0.161)	-0.12 (0.321)
Pragmatic user experience	4.25	0.92	1.00	5.00	-1.205 (0.161)	0.557 (0.321)
Privacy	1.61	0.76	1.00	5.00	1.187 (0.161)	1.159 (0.321)
Social interaction	3.79	1.06	1.00	5.00	-0.758 (0.161)	-0.148 (0.321)
Social participation	3.57	1.09	1.00	5.00	-0.525 (0.161)	-0.497 (0.321)
Stigma-free design	1.67	0.68	1.00	3.50	0.859 (0.161)	-0.328 (0.321)
Subjective state of health	3.95	0.87	1.70	5.00	-0.831 (0.161)	0.018 (0.321)
Subjectively relevant activity level	4.42	0.72	1.11	5.00	-1.797 (0.161)	3.809 (0.321)
Therapy adherence/-compliance	4.06	0.83	2.00	5.00	-0.388 (0.161)	-0.853 (0.321)

Table 9: Intercorrelations between the scales of the instrument for the evaluation of AAL technologies in the area of health (*p <.05, ** p<.01, *** p<.001)

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17
1. Life satisfaction	1																
2. Autonomy & self-determination	.515**	1															
3. Perception of safety	.683**	.485**	1														
4. Age(ing)-related self-image	.611**	.395**	.611**	1													
5. Subjective state of health	.795**	.607**	.644**	.557**	1												
6. Health-promoting behavior	.506**	.418**	.416**	.419**	.465**	1											
7. Social interaction	.644**	.342**	.515**	.422**	.505**	.260**	1										
8. Social participation	.628**	.358**	.463**	.472**	.550**	.292**	.824**	1									
9. Pragmatic user experience	.009	.062	.035	.027	.009	-.014	.154*	.170*	1								
10. Hedonic user experience	.041	.006	.046	.104	.027	-.006	.195**	.140*	.372**	1							
11. Stigma-free design	-.116	-.021	-.095	-.055	-.067	-.012	-.231**	-.205**	-.301**	-.140*	1						
12. Privacy	-.004	-.072	-.134*	-.010	-.032	-.047	-.104	-.023	-.010	.040	.166*	1					
13. Freedom of choice regarding service access	.079	.307**	.139*	.090	.130*	.197**	.075	.079	.141*	-.052	-.225**	-.244**	1				

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17
1. Life satisfaction	1																
14. Access & offer healthcare	.222**	.300**	.321**	.173**	.219**	.217**	.165*	.098	.004	.069	.048	-.081	.177**	1			
15. Affordability of health care	.181**	.169*	.289**	.157*	.194**	.134*	.152*	.189**	.020	.030	.025	-.091	.041	.356**	1		
16. Therapy adherence/-compliance	.334**	.297**	.272**	.264**	.276**	.374**	.252**	.223**	.082	.110	-.034	-.116	.187**	.339**	-.053	1	
17. Subjectively relevant activity level	.597**	.593**	.541**	.445**	.621**	.359**	.438**	.428**	.089	.036	-.107	-.078	.240**	.203**	.183**	.302**	1

4.2. Item Analysis: Item Parameters and Quality Criteria for the Questionnaire on Care & Support

Within the online study, which was conducted using Respondi (respondi.com), data were collected from 79 English native speakers living in the United Kingdom. Participation in the study was voluntary. For this sample, reading glasses and digital calendars were given as examples of assistive devices and technology in the formulation of the items.

The sample consisted of 34 female persons and 45 male persons with a mean age of 66.45 years (*SD* = 5.39). The majority of respondents (94.94%) stated that they use smartphones, computers, PCs, or similar devices on a daily basis; two persons (2.53%) uses such devices on a weekly basis; two persons (2.53%) uses such devices less frequently than monthly or never.

Item parameters were calculated on the basis of this sample and are presented in the following table. Specifically, mean values, standard deviations, and item-total correlations are shown here and the reliability (Cronbach's alpha) for the scales is specified. One item (AOH4 “I am willing to make use of health services”) has been removed due to low reliability. The reliability values of the final item set range from 0.232 to 0.896 for the item-total correlation. In detail, the item PUX1 is beyond the threshold of .300 but the item was not deleted due to relevance to the construct (ease of use for pragmatic UX). However, we recommend rechecking the reliability of the scale before analysis. Cronbach's alpha of all items ranges from 0.678 to 0.942.

Furthermore, we removed two scales (perception of safety and self-esteem) as well as the items SRA4-9 of subjectively relevant activities due to diffuse component loadings. We assume that the subjective relevance and quality of the specific activities vary too much to include them in one scale. We, therefore, recommend not including activity 2 (SRA4-6) and activity 3 (SRA7-9) in the scale values, but descriptive analyze these items. Nonetheless, these items may be useful to gain better insight as it is highly unlikely that older people receiving care or support consider only one activity alone to be central.

Table 10: Mean values, standard deviations, item-total correlation, and Cronbach’s alpha of the items of the instrument for the evaluation of AAL technologies in the area of care

Item	M	SD	Item-total correlation	Cronbach's Alpha
Access & offer healthcare				.871
AOH1	3.18	1.27	.773	
AOH5	3.68	1.18	.773	
Affordability of healthcare				.685
AH2	3.00	1.06	.524	
AH3	2.48	1.20	.524	
Age(ing)-related self-image				.740
ARSI1	3.41	1.06	.586	
ARSI2	3.27	1.09	.574	
ARSI3	2.66	1.10	.536	

Item	M	SD	Item-total correlation	Cronbach's Alpha
Autonomy & self-determination				.871
AS1	4.29	0.91	.804	
AS2	4.44	0.76	.747	
AS3	4.19	1.05	.751	
Freedom of choice regarding service access				.839
FC1	4.57	0.73	.723	
FC2	4.59	0.76	.723	
Health-promoting behavior				.683
HPB1	3.51	1.14	.432	
HPB2	4.14	0.96	.370	
HPB3	4.00	0.89	.750	
Hedonic user experience				.834
HUX2	3.09	1.29	.715	
HUX3	3.09	1.32	.715	
Life & health satisfaction				.932
LHS1	2.95	1.15	.786	
LHS2	2.86	1.20	.814	
LHS3	3.01	1.27	.772	
LHS4	3.38	1.18	.757	
LHS5	3.56	1.14	.742	
LHS6	2.77	1.10	.715	
LHS7	3.63	1.22	.723	
LHS8	3.22	1.29	.801	
Pragmatic user experience				.678
PUX1	4.37	0.95	.232	
PUX4	4.23	0.88	.643	
PUX5	4.37	1.00	.669	
Privacy				.861
PR1	1.91	1.16	.712	
PR2	1.78	1.11	.797	
PR3	2.23	1.25	.712	
Social interaction				.942
SI1	3.24	1.32	.895	
SI2	3.27	1.31	.896	
SI3	3.46	1.16	.854	
Social participation				.871
SP1	2.99	1.35	.808	
SP2	3.27	1.38	.767	
SP3	3.28	1.25	.690	
Stigma-free design				.782
SFD1	2.30	1.19	.575	
SFD3	2.33	1.05	.703	
SFD4	1.59	0.98	.467	
SFD5	2.18	1.00	.733	
SFD6	1.77	0.93	.476	
SFD7	2.78	1.29	.319	

Item	M	SD	Item-total correlation	Cronbach's Alpha
Subjectively relevant activity level				.778
SRA1	3.61	1.27	.748	
SRA2	4.25	0.97	.496	
SRA3	3.38	1.41	.654	
Therapy adherence/-compliance				.844
TAC1	4.18	0.78	.737	
TAC2	4.13	0.90	.737	

Dimensionality of the instrument

Furthermore, a principal component analysis was calculated for each area, i.e. the vitality & quality of life, social aspects, social system, and design & technology, if subscales included more than one item with the same rating system. Kaiser-Meyer-Olkin (KMO) and Bartlett's test of sphericity showed that the assumptions for a PCA are met.

For vitality & QoL, seven components have been identified, presented in Table 11.

Table 11: Rotated component loadings of "Vitality and Quality of Life" for the area of care (item loadings highlighted in gray)

	Life & health satisfaction	Autonomy & self-determi-nation	Age(ing)-related self-image	Health-promoting be-havior	Subjectively relevant activity level
SRA1	.167	.210	.102	.027	.875
SRA2	-.040	.750	.125	.054	.418
SRA3	.347	.183	.134	-.073	.788
AS1	.200	.896	.097	.107	.051
AS2	.046	.791	.223	.218	.244
AS3	.338	.783	-.036	.208	-.002
LHS6	.815	.012	.166	-.001	.114
LHS7	.624	.409	.293	.265	-.072
LHS8	.774	.316	.287	.095	-.072
LHS1	.787	.110	.210	.132	.177
LHS2	.861	.043	.160	.048	.228
LHS3	.830	.142	.148	-.070	.173
LHS4	.628	.058	.369	.294	.281
LHS5	.546	.221	.492	.283	.200
ARSI1	.144	.086	.765	.125	.223
ARSI2	.286	.077	.741	.084	.028
ARSI3	.337	.122	.696	-.097	.014
HPB1	.409	.201	.320	.489	-.036
HPB2	-.071	.108	-.074	.838	.041
HPB3	.211	.275	.175	.788	-.063

Based on the PCA, life satisfaction (LS1-5) and subjective state of health (LS6-8) are no longer two separate dimensions but form the subscale Life & health satisfaction. As mentioned above, the subjectively relevant activities items 4-9, self-esteem, and perception of safety have been removed due to diffuse component loadings. Thus, we identified five components: Life & health satisfaction, autonomy & self-determination, age(ing)-related self-image, health-promoting be-havior, and subjectively relevant activity level. It must be noted that several cross-loadings

occurred. However, these cross-loadings are in line with the definitions of the indicators, but we recommend calculating intercorrelations of the respective scales.

The PCA of the social aspects confirmed the dimensionality of the instrument, as shown in Table 12. Three components have been identified: Social participation, freedom of choice regarding service access, and social interaction.

Table 12: Rotated component loadings of "Social Aspects" for the area of care (item loadings highlighted in gray)

	Social interaction	Freedom of choice regarding service access	Social participation
SP1	.577	.711	.114
SP2	.346	.898	.099
SP3	.688	.454	.175
SI1	.914	.253	.124
SI2	.904	.255	.127
SI3	.820	.369	.213
FC1	.104	.151	.912
FC2	.185	.029	.913

The PCA of the social systems items is presented in Table 13.

Table 13: Rotated component loadings of "Social System" for the area of care (item loadings highlighted in gray)

	Access & offer healthcare	Therapy adherence/ compliance	Affordability of healthcare
AOH1	.91	.15	.15
AH2	-.04	.17	.90
AH3	.37	.02	.80
AOH5	.89	.29	.10
TAC1	.19	.90	.14
TAC2	.20	.90	.07

The PCA reveals an additional component: Two items (AH2, AH3) of access & offer healthcare form a separate component with low cross-loadings named affordability of healthcare. Hence, we identified three components: affordability of healthcare, therapy adherence/-compliance, and access & offer healthcare.

Finally, the PCA of the items operationalizing the design & technology aspects are presented in Table 14.

Table 14: Rotated component loadings of "Design & Technology" for the area of care (item loadings highlighted in gray)

	Privacy	Hedonic user experience	Stigma-free design	Pragmatic user experience
PUX1	-.359	.539	-.021	.064
HUX2	.040	.803	-.109	.181
HUX3	.023	.765	-.070	.257
PUX4	-.070	.218	-.118	.906
PUX5	-.076	.177	-.018	.929
SFD1	.082	-.132	.785	-.020
SFD3	.166	-.376	.736	-.182
SFD4	.557	-.528	.247	.058
SFD5	.252	-.360	.691	-.229
SFD6	.520	-.426	.272	-.116
SFD7	.084	.318	.747	.109
PR1	.861	-.126	-.008	.051
PR2	.860	-.020	.206	-.130
PR3	.834	.072	.128	-.094

Initially, only one subscale operationalized user experience (PUX1, PUX5, HUX1, HUX2). However, the PCA shows that hedonic and pragmatic user experiences have to be separated. In sum, four components have been identified: privacy, hedonic user experience, stigma-free design, and pragmatic user experience.

While the other components give a very clear structure, stigma-free design (SFD1-7) shows interesting cross-loadings with the hedonic and pragmatic UX. Especially in comparison to the other application domains and the differing cross-loading to them, this is an interesting indication of future research questions that can be further explored in empirical studies.

Descriptive statistics (standardization)

Means, standard deviations, skewness, and kurtosis of the scales can be found in the following table. The intercorrelations of the scales can be found in Table 16.

Table 15: Descriptive statistics for the scales of the instrument for the evaluation of AAL technologies in the area of care & support (the standard deviations of skewness and kurtosis are given in parentheses)

Scale	M	SD	Min	Max	Skewness	Kurtosis
Access & offer healthcare	3.43	1.15	1.00	5.00	-0.538 (0.271)	-0.575 (0.535)
Affordability of healthcare	2.74	0.99	1.00	5.00	-0.053 (0.271)	-0.694 (0.535)
Age(ing)-related self-image	3.11	0.88	1.00	5.00	-0.325 (0.271)	-0.036 (0.535)
Autonomy & self-determination	4.31	0.82	2.00	5.00	-1.104 (0.271)	0.601 (0.535)
Freedom of choice regarding service access	4.58	0.69	2.00	5.00	-1.74 (0.271)	2.615 (0.535)
Health-promoting behaviour	3.88	0.78	2.00	5.00	-0.463 (0.271)	-0.605 (0.535)
Hedonic user experience	3.09	1.21	1.00	5.00	-0.135 (0.271)	-0.609 (0.535)
Life & health satisfaction	3.17	0.98	1.00	5.00	0.03 (0.271)	-0.93 (0.535)
Pragmatic user experience	4.32	0.74	2.33	5.00	-0.96 (0.271)	-0.07 (0.535)
Privacy	1.97	1.04	1.00	5.00	1.062 (0.271)	0.562 (0.535)
Social interaction	3.32	1.20	1.00	5.00	-0.219 (0.271)	-0.992 (0.535)
Social participation	3.18	1.19	1.00	5.00	-0.255 (0.271)	-0.791 (0.535)
Stigma-free design	2.16	0.75	1.00	4.00	0.238 (0.271)	-0.75 (0.535)
Subjectively relevant activity level	3.75	1.02	1.00	5.00	-0.521 (0.271)	-0.619 (0.535)
Therapy adherence/-compliance	4.15	0.78	2.00	5.00	-0.585 (0.271)	-0.51 (0.535)

Table 16: Intercorrelations between the scales of the instrument for the evaluation of AAL technologies in the area of care & support (**p <.05, ** p<.01, *** p<.001)*

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
1. Access & offer healthcare	1														
2. Affordability of healthcare	.336**	1													
3. Age(ing)-related self-image	.259*	.159	1												
4. Autonomy & self-determination	.289**	.074	.298**	1											
5. Freedom of choice regarding service access	.369**	.004	.298**	.561**	1										
6. Health-promoting behaviour	.215	.225*	.327**	.458**	.050	1									
7. Hedonic user experience	.248*	.231*	.011	.080	.098	.101	1								
8. Life & health satisfaction	.493**	.303**	.606**	.460**	.301**	.443**	-.002	1							
9. Pragmatic user experience	.225*	.201	.090	.388**	.220	.384**	.420**	.078	1						
10. Privacy	-.232*	-.055	-.122	-.193	-.379**	.054	-.112	-.045	-.226*	1					
11. Social interaction	.430**	.185	.530**	.348**	.334**	.247*	.227*	.662**	.229*	-.079	1				
12. Social participation	.312**	.179	.596**	.262*	.308**	.301**	.099	.706**	.089	-.015	.799**	1			
13. Stigma-free design	-.149	-.031	-.124	-.313**	-.423**	-.064	-.317**	.070	-.339**	.445**	-.064	.060	1		
14. Subjectively relevant activity level	.239*	.036	.338**	.486**	.366**	.186	.174	.443**	.090	-.169	.268*	.336**	-.123	1	
15. Therapy adherence/-compliance	.428**	.255*	.349**	.498**	.404**	.552**	.168	.350**	.300**	-.087	.399**	.284*	-.240*	.158	1

4.3. Item Analysis: Item Parameters and Quality Criteria on Being active & Human Potential

Within the online study, which was conducted using Respondi (respondi.com), data were collected from 176 English native speakers living in the United. Participation in the study was voluntary. For this sample, reading glasses and digital calendars were given as examples of assistive devices and technology in the formulation of the items.

The sample consisted of 87 female persons and 89 male persons with a mean age of 65.18 years (*SD* = 5.13 The majority of respondents (96.59%) stated that they use smartphones, computers, PCs, or similar devices on a daily basis; each two persons (1.14%) uses such devices on a weekly or monthly basis; two persons uses such devices less frequently than monthly or never.

Item parameters were calculated on the basis of this sample and are presented in the following table. Specifically, mean values, standard deviations, and item-total correlations are shown here and the reliability (Cronbach's alpha) for the scales is specified. One item (AOH4 “I am willing to make use of health services”) has been removed due to low reliability. The reliability values of the final item set range from 0.373 to 0.864 for item-total correlations and 0.702 to 0.934 for Cronbach's alpha.

Table 17: Mean values, standard deviations, item-total correlation, and Cronbach’s alpha of the items of the instrument for the evaluation of AAL technologies in the area of being active & human potential

Item	M	SD	Item-total correlation	Cronbach's Alpha
Age(ing)-related self-image				.730
ARSI1	3.89	0.87	.575	
ARSI2	3.81	0.90	.575	
Autonomy & self-determination				.805
AS1	4.68	0.59	.682	
AS2	4.73	0.54	.765	
AS3	4.56	0.78	.582	
Digital inclusion				.885
DI1	4.18	0.81	.758	
DI2	4.11	0.95	.787	
DI3	4.25	0.84	.798	
Health control and competence				.844
HCS1	4.32	0.82	.650	
HCS2	4.14	0.83	.770	
HCS3	4.22	0.80	.698	
HCS4	3.84	1.01	.568	
HCS5	4.16	1.06	.471	
HCS6	4.09	0.85	.673	
Hedonic user experience				.887
HUX1	3.05	1.09	.798	
HUX2	3.01	1.13	.798	

Item	M	SD	Item-total correlation	Cronbach's Alpha
Life satisfaction				.934
LS1	3.97	1.02	.782	
LS2	3.90	1.04	.852	
LS3	3.99	0.98	.800	
LS4	3.98	1.08	.749	
LS5	4.01	0.99	.743	
LS6	3.73	0.95	.767	
LS7	3.08	1.27	.653	
LS8	3.69	1.08	.756	
LS9	3.97	1.08	.717	
Paid activity				.702
PA2	4.45	0.90	.556	
PA3	4.15	1.14	.556	
Pragmatic user experience				.779
PUX1	4.50	0.79	.373	
PUX4	4.11	1.09	.774	
PUX5	4.31	1.10	.773	
Privacy				.918
PR1	1.73	1.06	.864	
PR2	1.67	1.07	.850	
PR3	1.88	1.10	.790	
Social interaction				.903
SI1	3.88	1.02	.797	
SI2	3.84	1.08	.839	
SI3	3.94	1.02	.788	
Social participation				.860
SP1	3.80	1.11	.766	
SP2	3.69	1.22	.725	
SP3	3.86	1.03	.727	
Stigma-free design				.875
SFD1	2.41	1.19	.703	
SFD3	2.34	1.06	.697	
SFD4	1.53	0.93	.674	
SFD5	2.14	1.05	.771	
SFD6	1.81	1.06	.708	
SFD7	2.52	1.20	.556	
Subjective state of health				.808
SSH1	3.69	0.97	.522	
SSH2	4.19	0.88	.714	
SSH3	4.00	0.94	.751	
Subjectively relevant activity level				.883
SRA1	4.48	0.86	.639	
SRA2	4.74	0.56	.704	
SRA3	4.34	0.97	.564	
SRA4	4.58	0.74	.671	
SRA5	4.76	0.58	.600	

Item	M	SD	Item-total correlation	Cronbach's Alpha
SRA6	4.56	0.79	.585	
SRA7	4.51	0.84	.666	
SRA8	4.73	0.62	.710	
SRA9	4.49	0.86	.676	
Voluntary work				.808
VW2	4.43	0.70	.683	
VW3	4.36	0.79	.683	

Dimensionality of the instrument

Furthermore, a principal component analysis was calculated for each area, i.e. the vitality & quality of life, social aspects, social system, and design & technology, if subscales included more than one item with the same rating system. Kaiser-Meyer-Olkin (KMO) and Bartlett's test of sphericity showed that the assumptions for a PCA are met.

For vitality & QoL, seven components have been identified, presented in Table 18.

Table 18: Rotated component loadings of "Vitality and Quality of Life" for the area of being active & human potential (item loadings highlighted in gray)

	Life satisfaction	Subjectively relevant activity level	Health control & competence	Autonomy & self-deter-mination	Age(ing)-related self-image	Subjective state of health
SRA1	.085	.626	.145	.142	.360	-.005
SRA2	.048	.671	.185	.291	.113	.254
SRA3	.184	.575	.244	-.209	.405	.167
SRA4	.181	.636	.062	.426	.189	-.051
SRA5	.229	.537	.263	.338	-.001	.149
SRA6	.002	.591	.081	.232	.322	.023
SRA7	.226	.785	.062	.080	-.091	-.024
SRA8	.137	.774	.184	.197	-.144	.084
SRA9	.187	.807	.085	-.058	.010	-.006
AS1	.128	.210	.149	.766	.107	.159
AS2	.070	.259	.134	.806	.170	.107
AS3	.216	.190	.302	.597	.058	.035
SSH1	.291	.255	.186	-.010	.635	.306
SSH2	.398	.107	.165	.266	.136	.707
SSH3	.463	.197	.210	.268	.170	.626
LS1	.746	.184	.113	.087	.190	.285
LS2	.824	.194	.123	.038	.129	.236
LS3	.768	.207	.143	.105	.167	.177
LS4	.814	.076	.196	.177	-.038	-.123
LS5	.758	.140	.211	.169	.045	-.008
ARSI1	.177	.007	.001	.352	.703	.067
ARSI2	.287	.062	.047	.099	.688	.014
LS6	.690	.240	.145	.020	.362	.231
LS7	.685	.140	.035	-.142	.343	.044
LS8	.778	.065	.075	.104	.193	.087
LS9	.746	.063	.275	.195	.023	-.051
HCS1	.128	.181	.761	.187	-.029	.238
HCS2	.266	.275	.806	.060	.031	.104
HCS3	.121	.193	.828	.059	.062	.249

	Life satisfaction	Subjectively relevant activity level	Health control & competence	Autonomy & self-deter-mination	Age(ing)-related self-image	Subjective state of health
HCS4	.211	.080	.603	.137	.345	-.124
HCS5	.350	.144	.461	.212	-.203	-.355
HCS6	.276	.073	.619	.371	.184	-.201

Based on the PCA, life satisfaction (LS1-5) and self-esteem (LS6-9) are no longer two separate dimensions but self-esteem is part of the life satisfaction subscale. Further, the initially separated subscales perception of safety (HCS1-4) and health-promoting behavior HCS5-7) form the subscale health control and competence indicating how individuals set actions to control their health and safety and which competencies they use. Thus, we identified six components: life satisfaction, subjectively relevant activity level, health control & competence, autonomy & self-determination, age(ing)-related self-image, and subjective state of health. It must be noted, that several cross-loadings occurred. However, these cross-loadings are in line with the definitions of the indicators, but we recommend calculating intercorrelations of the respective scales.

The PCA of the social aspects confirmed the dimensionality of the instrument, as shown in Table 19. Four components have been identified: Social interaction, digital inclusion, freedom of choice regarding service access, and social participation.

Table 19: Rotated component loadings of "Social Aspects" for the area of being active & human potential (item loadings highlighted in gray)

	Social interaction	Digital inclusion	Freedom of choice regarding service access	Social participa-tion
SP1	.525	.217	.014	.712
SP2	.473	.127	-.034	.783
SP3	.786	.106	.056	.398
SI1	.840	.176	.109	.212
SI2	.875	.202	.067	.188
SI3	.871	.185	.032	.207
DI1	.127	.861	.128	.162
DI2	.136	.890	.128	.063
DI3	.270	.859	.134	.081
FC1	.078	.131	.970	-.010
FC2	.066	.189	.959	.006

Finally, the PCA of the items operationalizing the design & technology aspects are presented in Table 20.

Table 20: Rotated component loadings of "Design & Technology" for the area of being active & human potential (item loadings highlighted in gray)

	Stigma-free design	Privacy	Pragmatic user experience	Hedonic user experience
PUX1	-.205	.148	.579	.066
HUX1	-.044	.162	.187	.899
HUX2	-.006	.038	.169	.933
PUX4	.088	-.105	.889	.206
PUX5	.036	-.016	.914	.130
SFD1	.805	.091	.037	-.204
SFD3	.812	.096	.088	-.033
SFD4	.704	.276	-.363	.154
SFD5	.845	.153	-.053	-.009
SFD6	.786	.116	-.273	.145
SFD7	.654	.207	.102	-.019
PR1	.220	.904	.023	.094
PR2	.184	.918	-.046	.054
PR3	.212	.869	.055	.074

Initially, only one subscale operationalized user experience (PUX1, PUX5, HUX1, HUX2). However, the PCA shows that hedonic and pragmatic user experiences have to be separated. In sum, four components have been identified: stigma-free design, privacy, pragmatic user experience, and hedonic user experience.

Descriptive statistics (standardization)

The scales show a slightly skewed distribution for most variables. The kurtosis values varied between the scales. The following table presents these values as well as mean values and standard deviations. The intercorrelations of the scales can be found in Table 22.

Table 21: Descriptive statistics for the scales of the instrument for the evaluation of AAL technologies in the area of being active & human potential (the standard deviations of skewness and kurtosis are given in parentheses)

Scale	M	SD	Min	Max	Skewness	Kurtosis
Age(ing)-related self-image	3.85	0.78	1.50	5.00	-0.483 (0.183)	0.198 (0.364)
Autonomy & self-determination	4.65	0.55	2.00	5.00	-1.967 (0.183)	4.505 (0.364)
Digital inclusion	4.18	0.78	1.33	5.00	-0.879 (0.183)	0.771 (0.364)
Freedom of choice regarding service access	4.74	0.60	1.00	5.00	-3.234 (0.183)	13.317 (0.364)
Health control & competence	4.13	0.68	1.33	5.00	-0.781 (0.183)	0.86 (0.364)
Hedonic user experience	3.03	1.05	1.00	5.00	-0.091 (0.183)	-0.013 (0.364)
Life satisfaction	3.97	0.88	1.00	5.00	-0.896 (0.183)	0.589 (0.364)
Paid activity	4.30	0.90	1.00	5.00	-1.547 (0.203)	2.438 (0.403)
Pragmatic user experience	4.31	0.84	1.00	5.00	-1.403 (0.183)	1.676 (0.364)
Privacy	1.76	1.00	1.00	5.00	1.512 (0.183)	1.874 (0.364)
Social interaction	3.89	0.95	1.00	5.00	-0.815 (0.183)	0.194 (0.364)
Social participation	3.78	0.99	1.00	5.00	-0.642 (0.183)	-0.251 (0.364)
Stigma-free design	1.96	0.85	1.00	5.00	1.337 (0.183)	2.367 (0.364)
Subjective state of health	3.96	0.79	1.67	5.00	-0.596 (0.183)	-0.182 (0.364)
Subjectively relevant activity level	4.58	0.55	2.00	5.00	-1.857 (0.183)	4.446 (0.364)
Voluntary work	4.39	0.69	2.50	5.00	-0.726 (0.365)	-0.3 (0.717)

Table 22: Intercorrelations between the scales of the instrument for the evaluation of AAL technologies in the area of being active and human potential (*p <.05, ** p<.01, *** p<.001)

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
Autonomy & self-determination	1															
Life satisfaction	.375**	1														
Health control & competence	.493**	.499**	1													
Age(ing)-related self-image	.311**	.370**	.231**	1												
Subjective state of health	.448**	.615**	.446**	.471**	1											
Social interaction	.388**	.605**	.505**	.327**	.661**	1										
Social participation	.340**	.604**	.490**	.315**	.629**	.806**	1									
Pragmatic user experience	.170*	.244**	.242**	.103	.126	.133	.140	1								
Hedonic user experience	.050	.294**	.170*	.042	.212**	.226**	.185*	.323**	1							
Digital inclusion	.369**	.368**	.480**	.232**	.274**	.415**	.375**	.238**	.226**	1						
Stigma-free design	-.087	-.124	-.091	.093	-.001	-.055	-.024	-.147	-.020	-.045	1					
Privacy	-.202**	-.102	-.240**	.093	-.023	-.119	-.109	.013	.172*	-.125	.396**	1**				
Freedom of choice regarding service access	.337**	.100	.355**	.207**	.175*	.177*	.085	.356**	.110	.311**	-.071	-.111	1			
Subjectively relevant activity level	.488**	.442**	.469**	.294**	.492**	.399**	.361**	.204**	.034	.352**	-.106	-.200**	.213**	1		
Voluntary work	.627**	.521**	.386*	.237	.391*	.571**	.361*	.168	-.076	.461**	-.448**	-.391*	.292	.441**	1	
Paid activity	.308**	.568**	.431**	.335**	.393**	.423**	.370**	.465**	.238**	.227**	-.048	-.096	.291**	.308**	.369	1

5. Iterative Development of the Non-reactive Instruments

The methodological approach of EvAALuation² is characterized by approaches of the iterative development of concrete measuring instruments for the evaluation of AAL solutions. In addition to the questionnaire surveys on reactive data described above, which are obtained as a reaction to a research action among older/aging people, measuring instructions for non-reactive data were developed. These non-reactive methods make use of, for example, process-produced data, covert observations, content analyses, etc., whereby specific behavioral effects such as interviewer effects can be avoided (Diaz-Bone & Weischer 2015).
The quality features of the iterative development of the non-reactive measuring instruments were ensured through several processing steps, i.e. a comprehensive literature analysis, internal validation loops as well as interviews with competent and practice-oriented experts in two loops. This continuous process served to ensure appropriateness, completeness, and practicality.
With regard to the practical application, the determination of the survey process takes place by taking into account the time perspective. This ensures that all relevant parameters are recorded in the time sequence of a project test. In addition, the application areas of **health**, **care & support** as well as **being active & human potential** are of relevance, depending on which the relevant measurement parameters as well as the surveys of the same can differ in the course of the evaluation.

Within the framework of the comprehensive literature research, existing AAL projects were analyzed regarding applied non-reactive evaluation procedures. These are tests published within the framework of the Europe-wide programme *AAL - Active and Assisted Living Programme of the AAL Association (AALA)* and the national funding program *ICT of the Future: benefit – Opportunity through Demographic Change* of the Austrian Research Promotion Agency (FFG). Additionally, relevant methodological documents were researched, which formulate guidelines for the collection of data or give information on potential difficulties. These also include definitions of basic concepts as well as classifications such as different R&D cost types (based on OECD 2015). Particularly with regard to the cost parameters, it must be pointed out that these are relevant for an overall evaluation of the AAL solution and must be considered in relation to further effects.
Drawing on this in terms of content, internal project coordination processes and revision loops took place to create a concept for the presentation of the measuring instructions, which contains the following relevant basic information:

Definition: The exact definition of the indicator to be surveyed was included in the measuring instructions in order to either clearly distinguish or combine supposedly similar or synonymously used terms. The definitions must be as simple and universally defined as possible so that potential users can understand and use them immediately.

Data source: Information on the potential data source serves to obtain possible conclusions about data availability. Possible data sources for determining non-reactive data in the context of AAL are, for example, the providers or developers of an AAL product or an AAL service. In addition, statistical offices or the users themselves can be relevant,

provided that data are collected non-reactively (e.g. covert observation during active/passive usage).

Object of measurement: The object of measurement specifies what is to be measured in detail. In so doing, the respective measured quantities that are considered relevant for the respective application area are described (e.g. number of hospital days in the application area health).

Time of measurement: The time of measurement includes a suggestion of when and, if necessary, how often the measurement should be carried out for a particular indicator. Depending on the measured quantity, the particular point in time may vary and in some cases, multiple measurements in control and intervention groups are necessary to obtain valid results.

Measurement mode: Information on the type of measurement is particularly relevant as, depending on the indicator, different types of data (quantitative data as well as qualitative data) can be used to determine the same (e.g. paper or online questionnaires, telephone or personal interviews).

Further notes: Special notes that should be considered when using the respective measuring instructions are given.

In a downstream step, potential experts were identified and the measuring instructions were then validated by them. Care was taken to ensure that the experts chosen to evaluate the respective indicators came from relevant fields (e.g. medical technology and cost accounting). During the interviews, the focus was on the validity and relevance of the developed measuring instructions, whereby general practice-oriented feedback was also requested. On the basis of this, the measuring instructions were revised and validated again by specific experts in order to make final revisions if necessary.[2]

In the expansion pack of 3vAALuation, the non-reactive measurement instruments were supplemented by the English translation. In terms of content, cost, performance, and financing specifics, as well as ethical aspects, were analyzed in the context of the respective health and care systems of the 14 European countries of the AAL Europe Call 2020. Publications and reports of international institutions (e.g. World Health Organization (WHO)) or associations (e.g. European Union (EU)) served as a basis, although national sources were also included

[2] Within the framework of the expert interviews, the following persons were interviewed between the beginning of April and the beginning of May and asked for feedback: Dipl.-Ing.in Daniela Krainer (Senior Researcher/Lecturer & Head of the Active & Assisted Living Research Group, Department of Engineering & IT; Carinthia University of Applied Sciences; Villach, 04 April 2019), FH-Prof.in Mag.a Hermine Bauer (Professor of Business Administration; Department of Economics & Management, Carinthia University of Applied Sciences; Villach, 15 April 2019), Univ.- Prof. Dr. Gerald J. Pruckner (Head of the Department of Health Economics, University Professor at the Institute of Health Economics, Carinthia University of Applied Sciences; Villach, 15 April 2019). Prof. Dr. Gerald J. Pruckner (Head of the Department of Health Economics, University Professor at the Institute of Economics, JKU Linz; Neuhofen an der Krems, 26 April 2019), Dipl.-Ing. Kurt Majcen (Project Manager, Joanneum Research; telephone interview on 06 May 2019).

in the analysis. Based on this, the following categories were formed, which in turn lead to the non-reactive measurement instruments concerned:

Short description: Type of publicly funded health and care system since the structure (e.g., Bismarck or Beveridge, centralized or federal) is considered to be important in the comprehensive implementation of new technologies.

Health & Care provision: Overview of the organization, tasks, and services of the public health and care system, or which service must be paid out-of-pocket or via private insurance.

Financing & Reimbursement: Information on funding and reimbursement to identify potentially relevant stakeholders who need to be involved in widespread implementation.

Data Protection & Ethical Issues: Presentation of laws and regulations but also ethical aspects discussed so far implementing innovative technologies.

Health Technology Assessment: Provides information and guidelines regarding the application and implementation of Health Technology Assessment in the respective country. Based on this, Databases and country-specific information embedded in the existing non-reactive measurement tools that could contribute to the determination at the national level.

Databases and country-specific information: Country-specific information is needed when applying the respective indicator. Links forward to specific international and national laws, regulations, guidelines, and databases.

After consultation with the Federal Ministry for Climate Action, Environment, Energy, Mobility, Innovation and Technology (BMK) and the Austrian Research Promotion Agency (FFG), Italy, the Netherlands, Romania and Switzerland were selected for further analysis on the basis of these results. Selection criteria for this included demographics, broadband internet access, research cooperation with Austria within the AAL Programme. In addition to the analysis of the medical and nursing pre- and care system, a benchmarking was carried out on the four selected countries, focusing mainly on the area of formal and informal care. According to recent population forecasts, more and more aging and elderly persons will need informal and formal care in the future, and countries, states, regions (e.g. urban and rural), or even cultures sometimes differ considerably in terms of the share of formal and informal care. Benchmarking will provide an overview with regard to the supply situation of formal and informal care and will also analyze the different funding structures and areas of responsibility (e.g., national, federal, municipal) and discuss which application areas are most relevant for each country. By following this approach, the operationalization of relevant key figures and indicators - depending on the respective nation – is carried out step by step and the basis for the further analysis created.
The exemplary evaluation of selected monetized non-reactive measurement instruments according to the respective characteristics of the four countries was carried out as a conclusion. This approach follows the objective to show on the basis of a specific technical solution, which different framework conditions in the respective countries influence the (financing) decision for the area-wide implementation of an AAL solution, whether there are different needs due to the medical and nursing and preventive and care system, and which (economic and social) obstacles have to be overcome in the respective countries.

PART B – Measuring Instruments

Part B presents the developed instruments separately for the areas of health, care & support as well as being active & human potential. First, the scope of application is defined in order to subsequently describe the operational definitions of the individual indicators and sub-scales. Afterward, the reactive instruments, i.e. the questionnaires, for the respective application area as well as the survey instructions for the non-reactive key figures, which are not collected through surveys, are presented.

1. *Instructions for International Studies*

Public administration and finance schemes are of particular interest for health and care, especially concerning the ongoing process of implementing eHealth, digital health, Ambient Assisted Living or Active & Assisted Living (AAL) solutions and technologies in our daily lives. Its importance will remain stable or increase even more as health and care systems become more complex due to aging societies. In total, in 2020, 16 countries were part of the AAL Programme. These are predominantly located in Europe, but Canada and Taiwan are also joining. The multinational approach creates a diverging social, economic and legal environment and therefore varying underlying conditions for the successful implementation of technologies, services, and products. For this reason, this chapter deals with national frameworks of the European AAL Programme countries of 2020. There is a special and spatial (in regard to the regions) interest in the costs and funding schemes, health and care system typologies, differences in the scale and scope of urban and rural development, but also legal (especially data protection) and ethical issues for new techniques, as those are relevant for its successful and extensive introduction.

Economic situations and spending on health care vary among European AAL countries (see Table 23. Similarly, curative care and rehabilitative care per capita and long-term care per capita and their corresponding growth rates (2011-2019) for the mentioned countries differ significantly (see Figure 2). For example, countries like Switzerland, Austria, Netherlands, and Luxembourg have high per capita expenditures for curative care and rehabilitative care. On the other hand, Romania, Poland, and Portugal have very high, sometimes double-digit, yearly growth rates. For instance, in Romania, the annual growth rate was 20.4 % from 2016 to 2017 and 22.3 % from 2017 to 2018, although the starting level of per capita expenditures for curative care and rehabilitative care was very low compared to the European AAL Programme countries.

Table 23: GDP and expenditure on health in European AAL Programme countries of 2020, 2018

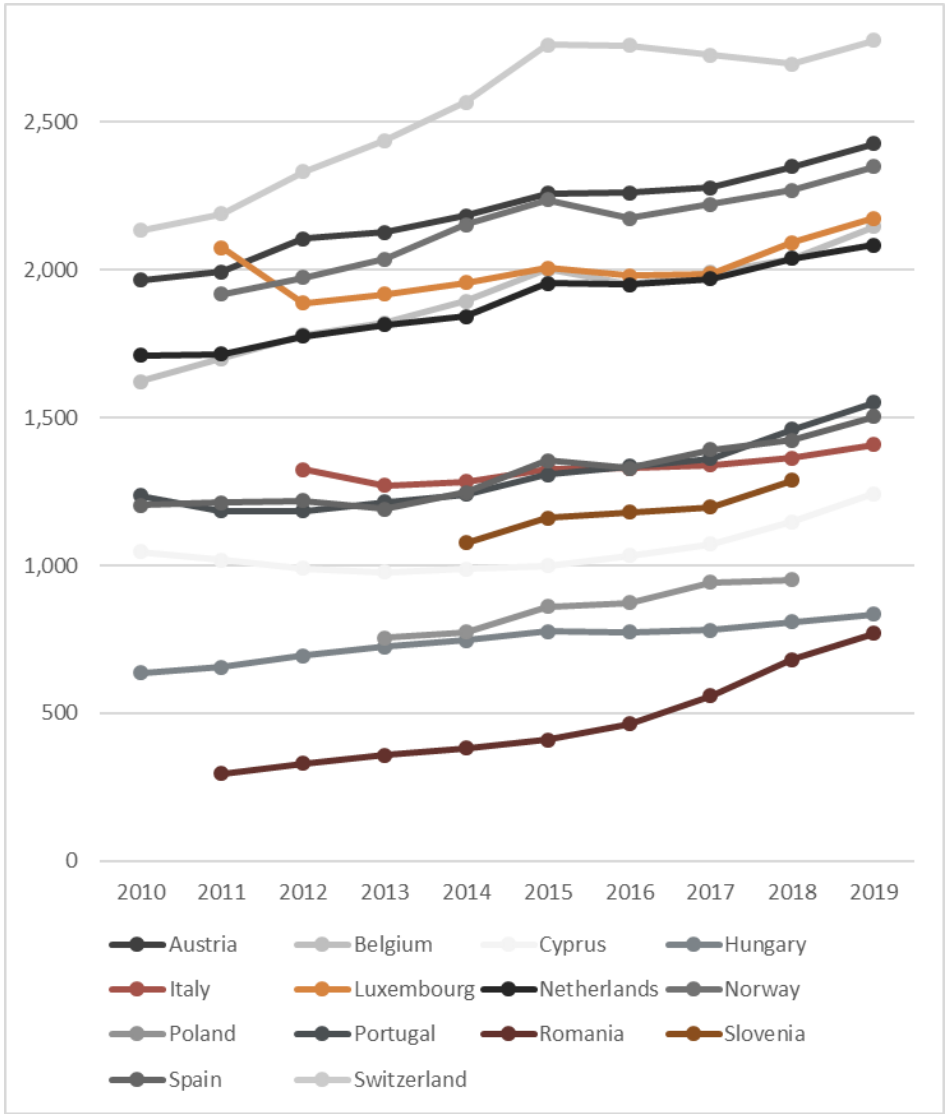
Country	GDP per capita (current US$)	Total health expenditure per capita (current US$)	Total health expenditure (% of GDP)	Public health expenditure (% of Total health expenditure)	Private health expenditure (% of Total health expenditure)	Public health expenditure (% of GDP)	Private health expenditure (% of GDP)
Austria	51,453	5,326	10.3	73.1	26.9	7.5	2.8
Belgium	47,555	4,913	10.3	75.8	24.2	7.8	2.5
Cyprus	29,089	1,954	6.8	43.2	56.8	2.9	3.8
Hungary	16,411	1,082	6.7	69.1	30.9	4.6	2.0
Italy	34,609	2,989	8.7	73.9	26.1	6.4	2.3
Luxembourg	116,597	6,227	5.3	86.3	13.7	4.5	0.7
Netherlands	53,019	5,307	10.0	64.9	35.1	6.5	3.5
Norway	82,268	8,239	10.0	85.3	14.7	8.6	1.5
Poland	15,468	979	6.3	71.1	28.9	4.5	1.8
Portugal	23,551	2,215	9.4	61.5	38.5	5.8	3.6
Romania	12,399	687	5.6	79.7	20.3	4.4	1.1
Slovenia	26,103	2,170	8.3	72.4	27.6	6.0	2.3
Spain	30,375	2,736	9.0	70.4	29.6	6.3	2.7
Switzerland	86,430	9,871	11.9	31.2	68.8	3.7	7.9

Source: World Bank DataBank (2021), own calculations and illustration

The relationship between public and private health expenditure is of special interest as there is a broad range in European AAL Programme countries of 2020: Public health expenditure in Luxembourg (86.3 %), Norway (85.3 %), and Romania (79.7 %) are the highest whereas Belgium (75.8 %), Italy (73.9 %), Austria (73.1 %), Slovenia (72.4 %), Poland (71.1 %) and Spain (70.4 %) are on a comparable medium level. Vice versa, a low percentage of public health expenditure causes high private health expenditures. In Switzerland, 68,8 % of health expenditures are privately paid (versus 31,2 % publicly); almost the same applies to Cyprus (56.8 % vs. 43.2 %). Moreover, in Portugal (38.5 % vs. 61.5 %), the Netherlands (35.1 % vs. 64.9 %), and Hungary (30.9 % vs. 69.1 %), the share of private health expenditures in total health expenditures is still high.

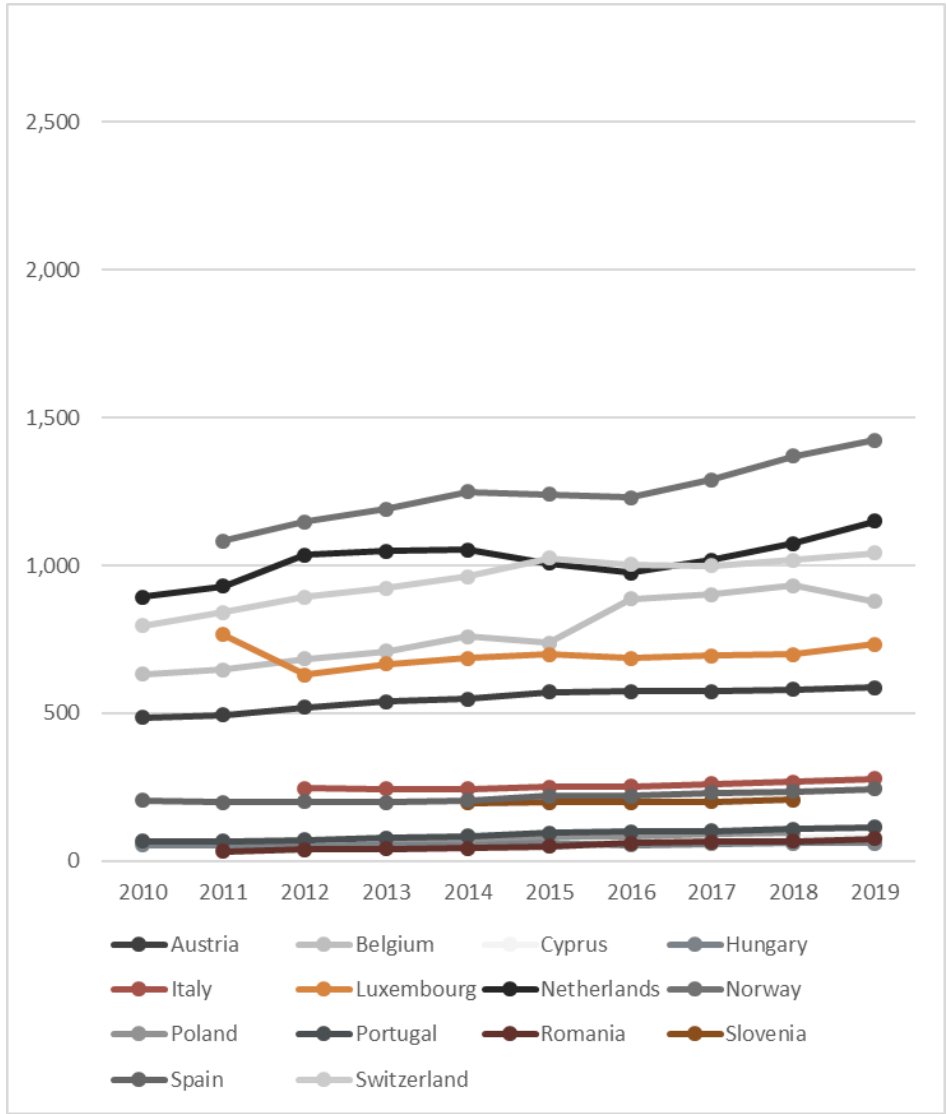
In 2013 and 2018, the European Commission analyzed the deployment of so-called eHealth technologies by a quantitative empirical investigation among general practitioners within selected countries of the European Union (2013 for the Netherlands only) and European Free Trade Association (2013 for Norway only); no data available for Switzerland neither 2013 nor 2018.

Figure 2: Curative care and rehabilitative care, 2010-2019



Source: Eurostat (2021a), own calculations and illustration

Figure 3: Long-term care, 2010-2019



Source: Eurostat (2021a), own calculations and illustration

Table 24: eHealth adoption by type of health system and country, 2018

Country	Health Care System	eHealth	EHR	HIE	Tele-health	PHR
Austria	SHI	1.914	2.975	1.778	1.679	1.203
Belgium	SHI	2.067	3.203	2.280	1.412	1.302
Cyprus	NHS	1.934	2.728	1.673	1.998	1.191
Hungary	SHI	2.028	2.951	1.845	1.996	1.327
Italy	NHS	2.185	3.356	2.081	1.709	1.549
Luxembourg	SHI	1.776	2.866	1.468	1.378	1.386
Netherlands (2013)	*SHI*	*2.121*	*3.329*	*2.190*	*1.537*	*1.462*
Norway (2013)	*NHS*	*2.158*	*3.013*	*2.738*	*1.151*	*1.730*
Poland	SHI	1.837	2.635	1.394	1.726	1.455
Portugal	NHS	2.118	3.062	2.206	1.425	1.754
Romania	SHI	1.788	2.608	1.572	1.759	1.186
Slovenia	SHI	1.998	2.504	1.872	1.788	1.719
Spain	NHS	2.365	3.384	2.424	1.888	1.763
Switzerland	SHI	-	-	-	-	-

Source: European Commission (2018) and European Commission (2013)

eHealth (electronic health technologies), dHealth (digital health technologies), and AAL (Active & Assisted Living) are vague terms under which a variety of technical solutions in the medical and care context are subsumed. Respectively, the authors of the studies differentiate between four main categories resulting in four composite indicators of eHealth:

- **Electronic health record (EHR)** adoption consists of five subdimensions, i.e. (1) health and info data, (2) clinical decision and support system, (3) order-entry and result management, (4) image and (5) administrative
- **Health information exchange (HIE)** adoption consists of three subdimensions, i.e. (1) clinical data, (2) patient administration, and (3) management
- **Telehealth** adoption consists of two subdimensions, i.e. (1) clinical practice and (2) training
- **Personal health record (PHR)** adoption consists of two subdimensions, i.e. (1) clinical information and (2) requests

While EHR and HIE composite indicators have high values and reflect good adoption, the opposite applies to telehealth and PHR. By equally weighting each composite indicator, you get the average score of the overall eHealth adoption, i.e. **eHealth composite index of adoption**. Therefore, it balances the high adoption of EHR and HIE with the low adoption of Telehealth and PHR. The values range from no awareness of adoption (0) to full awareness of adoption (4) stated among general practitioners.

The composite index for the EU (all member states of 2018 except for the Netherlands) is 2.131, indicating an increase since 2013 (plus 255 from 1.876). The AAL Europe Programme countries with the highest levels of eHealth adoption are Spain (2.365), Italy (2.185), and Portugal (2.118). Norway (2.158) and the Netherlands (2.121) rank at the top, though the values

are from the analysis in 2013. Under the assumption of an increase in technological development, you can expect these countries to rank at the top in 2018 as well. On the other hand, emerging economies as Romania (1.788), Poland (1.837), and Cyprus (1.934) have, together with Luxembourg (1.776), the lowest level of adoption.

While national governments across developed countries provide, structure, and/or fund health and care services, their direct involvement can vary widely. In general, two main models of healthcare systems prevail within European countries: (1) National health service (NHS), a model primarily funded by taxes and government-led. (2) Social health insurance (SHI), a model whereby citizens typically join or are assigned to one or more compulsory health insurance plans and pay for these a part of their income from employment.

As you can see from the table above, countries applying an NHS system are associated with a higher uptake of technological innovations in health and care. According to Brennan (2015), this is probably because of a smaller number of institutes to be involved in an implementation process. In comparison, social health insurance (SHI) models are characterized by a decentralized structure and, therefore, local governments, provinces, regions, municipalities, etc., have to be taken into account.

For this reason, the following country briefs summarize findings on institutional factors. The analysis includes country-specific information regarding **Health & Care Provision**, **Financing & Reimbursement**, **Data Protection & Ethical Issues**, and **Health Technology Assessment** identified as push-pull factors concerning a successful implementation of eHealth, dHealth, AAL technologies, and solutions. The categories above cross-reference to non-reactive measuring instruments (e.g. Market Potential) of the application areas Health, Care and Being Active for which they are most relevant

1.1. Austria

Austria has a Bismarck model of a health system based on general and compulsory social insurance, i.e., social health insurance (SHI). It covers 99 % of the population (Berger 2017; Lupiañez-Villanueva et al. 2018).

Health & Care Provision in Austria

Because of the federalist structure and the system of compulsory insurance, numerous actors from the different legislative and administrative levels and from the self-administration sector (social health insurance (SHI)) are involved in health and care provision (BMASGK 2019).

The central government is responsible for the general health provision, funding, and legislation of hospitals, while provinces are responsible for implementation and enforcement for hospitals but also for the care and social issues; thus, care responsibility splits between the federal and local governments as provinces should provide a minimum nationwide standard of long-term care (LTC). Types of care are mobile care services, residential care facilities, part-time care services, short-term care services in residential care facilities, and case & care management. SHI carries out the provision of services in the extra-mural sector, medicines, medical goods, and inpatient and outpatient rehabilitation (BMASGK 2019). Austria lacks gatekeeping and offers unlimited access to health services. Patients can directly access nearly any inpatient or outpatient specialist with no personal financial accountability (Hoffmann et al. 2019).

A government institution provides eHealth primarily focusing on electronic health records (EHR) called ELGA, though also developing the health and care sector by improving the integration of technological solutions into the publicly-funded system. The Ministry for Labour, Social Affairs and Consumer Protection has commissioned the computer application Pflegegeld-information (PFIF; i.e., care allowance information) used by the Main Association of Austrian social insurance institutions. Introducing PFIF strengthens and upgrades the existing system (European Commission 2019a; Bachner et al. 2018; Brandstätter 2020; BMASGK 2019).

Please note the following non-reactive instruments for which **Health & Care provision** is of great importance:

- ***Costs and Revenues during Development and Market Launch*** (see 115 in Health, page 168 in Care and page 222 in Being Active)
- ***Market Potential*** (see page 124 in Health, page 177 in Care and page 231 in Being Active)
- ***Avoided Resource Requirements*** (see page 128 in Health, page 181 in Care and page **Fehler! Textmarke nicht definiert.** in Being Active)
- ***Economic Potential from Increased Labour Market Participation and Voluntary Activity*** (see page 235 in Being Active)

Financing & Reimbursement in Austria

In 2019, healthcare is predominantly financed through compulsory contributory health care financing schemes (44.7 %) and government schemes (30.5 %), with an additional 17.7 % from out-of-pocket payments (OOP). Most public funding comes from the social health insurance schemes, while the contribution of voluntary health insurance (VHI) is 7.1 % (Eurostat 2021b).

The social health insurance (SHI) system exclusively finances the extramural health sector; the public purse and the social insurance funds share the costs in the intramural sectors. Taxes and insurance-based revenues finance compulsory health insurance. Health insurance funds also participate in the funding of hospitals by transferring a fixed share of their resources (about 35 %) to the states' hospital funds. The implementation of the health insurance system is carried out based on federal legislation by the social insurance funds in their sphere of activity. In addition, contract services in the extramural sector, medicines and medical goods, and inpatient and outpatient rehabilitation are included (BMASGK 2019).

ELGA (Elektronische Gesundheitsakte; i.e., electronic health record) is the leading information system responsible for the development of eHealth in Austria now. As a joint institution, the federal government, the regional governments, and the social health insurance (SHI) finance it (Hammerschmid et al. 2018; Austrian Health Targets 2019; European Commission 2019a; Berger 2017; Lupiañez-Villanueva et al. 2018).

Please note the following non-reactive instruments for which **Financing & Reimbursement** is of great importance:

- ***Human Assistance Costs*** (see page 110 in Health, page 163 in Care and page 217 in Being Active)
- ***Financial Burden for Users*** (see page 112 in Health, page 165 in Care and page 219 in Being Active)
- ***Operating Materials and Maintenance Costs*** (see page 119 in Health, page 172 in Care and page 226 in Being Active)
- ***Investment, Installation and De-installation Costs*** (see page 122 in Health, page 175 in Care and page 229 in Being Active)

Data Protection & Ethical Issues in Austria

No law refers specifically to eHealth, dHealth, AAL, etc., which lists all specifications needed. Depending on the area of application, a large number of laws and rules apply like the Physicians Act, the Hospital and Spa Act, the General Data Protection Regulation (GDPR), and the Health Telematics Act, which must always be taken into account when health data is regularly processed electronically. When selecting platforms or providers, care must be taken above all to ensure that encrypted data transmission is guaranteed.

Up to the Physicians Act, special attention must be paid to the principle of immediacy when assessing the admissibility of telemedical treatments. Though telemedicine enables immediacy, purely remote treatments are not feasible in principle. Therefore a minimum of personal interaction guarantees a certain immediacy meaning that the physician has already examined the patient at least once physically in his practice and subsequent treatments via telemedicine not associated with a loss of quality. Up to now, there are no guidelines, laws, etc., defining telemedical treatment in the sense of quality preservation. This assessment must be made by the treating physician, without her/him being able to refer to corresponding studies or other guidelines. Another advantage of telemedicine can be the comprehensive data material obtained available for medical research by applying respective legal basis and/or anonymization (Raabe-Stuppnig 2020).

The Health Telematics Act emphasizes technical data security measurements for the transmission of health data among service providers. It has to be ensured that health data is saved in storage that is provided based on the needs of clients only if the health data has been encrypted using appropriately modern and sufficient technology (Knyrim 2019). This Act also contains detailed regulations on the operation of electronic health record (EHR; Hebenstreit 2021).

Please note the following non-reactive instruments for which **Data Protection & Ethical Issues** are of great importance:

- ***Consideration of Ethical Guidelines*** (see page 94 in Health, page 147 in Care and page 201 in Being Active)
- ***State of Health*** (see page 98 in Health, page 151 in Care and page 205 in Being Active)
- ***Active/Passive Usage*** (see page 103 in Health, page 156 in Care and page 210 in Being Active)
- ***Error Data*** (see page 106 in Health, page 159 in Care and page 213 in Being Active)

Health Technology Assessment:

A national Health Technology Assessment (HTA) strategy was published in 2010, establishing common goals of the major decision-makers in the health and care sector and creating a framework for expanding the use of HTA (European Commission 2019a). Twelve recommendations for action include the definition of areas for the use of HTA, HTA in the context of target steering health, the definition of processes, criteria for topic identification (identification, preselection, prioritization, and selection), preparation of HTA reports, evaluation of the processed information and derivation of recommendations, decision and uniform implementation in the health care system, communication and dissemination of the results (BMSGPK 2020).

1.2. Belgium

Belgium has a Bismarck health system model based on general and compulsory social insurance. It covers 99 % of the population and organizes in five private, not-for-profit national associations of sickness funds (Berger 2017; Lupiañez-Villanueva et al. 2018).

Health & Care Provision in Belgium

Because of Belgium's federalist structure based on compulsory health insurance, jurisdiction regarding health issues and regulation split between the national and provincial/regional level. The central government (Ministry of Health) is in charge of general topics such as compulsory health insurance, hospital budget, organization and regulation of health products, services, professionals, and patient's rights. The National Institute for Health and Disability Insurance manages compulsory health insurance (Gerkens and Merkur 2020).

The provision of health and care relies on the principles of independent medical practice, direct access (no gatekeeping by general practitioners (GPs)), free choice of physicians and health care facilities (including hospitals), and predominantly fee-for-service payment (European Commission 2019a). Mainly the provision of health and care is a responsibility of the federal government and its communities. The core principle of the Belgium health care system is an independent medical practice with direct access to the service. In addition, medical specialists can work on an ambulatory basis in private for-profit clinics (called extramural centers). As these extramural centers do not comply with the strict licensing standards and criteria embedded in the Hospital Law, they are no hospitals. Nevertheless, physicians must follow the deontological rules and must guarantee the quality of care for their patients (Gerkens and Merkur 2020).

Care works via social service provision. Private nonprofit organizations offer formal care while the state sets the framework and standards. Long-term care provisions are fragmented because of a division of competencies between the federal government (responsible for medical care through the health and care system) and the communities (responsible for non-medical care). Provided types of care are home care, day care, short-stay care, nursing care, and personal care (European Commission 2019a; De Raedt 2021).

eHealth is promoted and supported by the government and is currently under further development. Some realizations were fulfilled from 2013 to 2018, and the new eHealth 2019-2021 Action Plan was approved at the beginning of 2019 (E-gezondheid 2020).

Please note the following non-reactive instruments for which **Health & Care provision** is of great importance:

- ***Costs and Revenues during Development and Market Launch*** (see 115 in Health, page 168 in Care and page 222 in Being Active)
- ***Market Potential*** (see page 124 in Health, page 177 in Care and page 231 in Being Active)
- ***Avoided Resource Requirements*** (see page 128 in Health, page 181 in Care and page **Fehler! Textmarke nicht definiert.** in Being Active)
- ***Economic Potential from Increased Labour Market Participation and Voluntary Activity*** (see page 235 in Being Active)

Financing & Reimbursement in Belgium

In 2019, healthcare is predominantly financed through compulsory contributory health care financing schemes (54.8 %) and government schemes (22.0 %), with an additional 18.2 % from out-of-pocket payments (OOP). Most public funding comes from the social health insurance schemes, while the contribution of voluntary health insurance (VHI) is 5.0 % (Eurostat 2021b).

The central government and its authorities are responsible for regulating and financing compulsory health insurance schemes, i.e., the funding of hospital budgets, legislation covering professional qualifications, and pharmaceuticals' registration and price control. The provinces are responsible for the financing of health infrastructure and medico-technical services, the definition of recognition norms for hospitals, health promotion and prevention, health workforce planning, maternity and child health care, social services, coordination in primary care, elderly care, mental health care, and long-term care (Hammerschmid et al. 2018; World Health Organization. Regional Office for Europe 2016; OECD/European Observatory on Health Systems and Policies 2019; Beneluxa n.d.).

Please note the following non-reactive instruments for which **Financing & Reimbursement** is of great importance:

- ***Human Assistance Costs*** (see page 110 in Health, page 163 in Care and page 217 in Being Active)
- ***Financial Burden for Users*** (see page 112 in Health, page 165 in Care and page 219 in Being Active)
- ***Operating Materials and Maintenance Costs*** (see page 119 in Health, page 172 in Care and page 226 in Being Active)
- ***Investment, Installation and De-installation Costs*** (see page 122 in Health, page 175 in Care and page 229 in Being Active)

Data Protection & Ethical Issues in Belgium

Diagnosing patients without the presence of both the physician and the patient in the same place poses risks, and therefore telemedicine would only be justifiable in exceptional cases, while telemonitoring or teleexpertise between physicians without diagnosing could be performed at a distance. Due to the pandemic of Covid-19, telehealth services could be performed with the patient's informed consent, end-to-end encryption, patient's physical and mental ability to attend the consultation at a distance, guaranteeing continuity of care and safeguarding the quality of care. Telemedicine provided under the aforementioned conditions was reimbursed by the National Institute for Health and Disability Insurance (Van Obberghen et al. 2021).

The liability of digital platform providers for copyright breaches and other infringements has been limited. Reimbursement schemes are limited to a few specific products classified as medical devices but non-existent for others. General Data Protection Regulation (GDPR) requires transparency, but users of such products are scarcely aware for which purposes their personal data are being used and with whom such personal data can be shared. Often at the beginning of the clinical trial (first use) when the consent of the data subject is sought, it is not yet entirely clear for which further research purposes the personal data may also be used (Van Obberghen et al. 2021).

Please note the following non-reactive instruments for which **Data Protection & Ethical Issues** are of great importance:

- ***Consideration of Ethical Guidelines*** (see page 94 in Health, page 147 in Care and page 201 in Being Active)
- ***State of Health*** (see page 98 in Health, page 151 in Care and page 205 in Being Active)
- ***Active/Passive Usage*** (see page 103 in Health, page 156 in Care and page 210 in Being Active)
- ***Error Data*** (see page 106 in Health, page 159 in Care and page 213 in Being Active)

Health Technology Assessment:
The Belgian Health Care Knowledge Centre has played a major role in conducting and gathering information on health technology assessment since 2003. Health technology assessment information has been used to define guidelines and determine coverage and level of reimbursement of new procedures, new medicines, and new high-cost equipment (European Commission 2019a). The Belgian Health Care Knowledge Centre (KCE) has published and updated guidelines regarding this topic in 2012 (Cleemput et al. 2012).

1.3. Cyprus

The Cypriot health system divides up two uncoordinated sub-systems of similar size: a public and a private one. There is no implemented coherent framework matching particular public and private healthcare services provisions, leading to inadequate and ineffective coverage. The public system is highly centralized. Planning, organization, administration, and regulation are in charge of the Ministry of Health (European Commission 2019a).

Health & Care Provision in Cyprus

Central government via the Ministry of Health is responsible for whole public health system provision, legislation, management, and control. Privates health and care services cover a high percentage of the health care sector. eHealth strategy is under development and implementation. The Ministry of Health and the Ministry of Labour, Welfare, and Social Insurance are responsible for managing care issues. In addition, the government, local authorities, non-governmental organizations (NGOs), and the private sector provide long-term social care services (European Commission 2019a; Theodorou 2014; Theodorou et al. 2012; Wavestone 2019).

Please note the following non-reactive instruments for which **Health & Care provision** is of great importance:

- ***Costs and Revenues during Development and Market Launch*** (see 115 in Health, page 168 in Care and page 222 in Being Active)
- ***Market Potential*** (see page 124 in Health, page 177 in Care and page 231 in Being Active)
- ***Avoided Resource Requirements*** (see page 128 in Health, page 181 in Care and page **Fehler! Textmarke nicht definiert.** in Being Active)
- ***Economic Potential from Increased Labour Market Participation and Voluntary Activity*** (see page 235 in Being Active)

Financing & Reimbursement in Cyprus

In 2019, a fully e-based single-payer health system (NHS) was introduced. The Ministry of Health is responsible for the budget suggestions to the Ministry of Finance, which asks the Council of Ministers and Parliament for approval. Therefore, the financing is mainly state-based (42.1 % of total healthcare spending in 2019); it is supported by contributions to health insurance from civil servants and civil servant pensioners (14.4 %). However, people tend to use private resources and pay out-of-pocket (30.6 %) to skip long waiting lines in public hospitals, while the contribution of voluntary health insurance (VHI) is 5 %. General NHS's used reimbursement scheme pre-assigns a percentage sub budget to different medical activities (European Commission 2019a; Hammerschmid et al. 2018; Petrou 2021; Eurostat 2021b).

Please note the following non-reactive instruments for which **Financing & Reimbursement** is of great importance:

- ***Human Assistance Costs*** (see page 110 in Health, page 163 in Care and page 217 in Being Active)
- ***Financial Burden for Users*** (see page 112 in Health, page 165 in Care and page 219 in Being Active)
- ***Operating Materials and Maintenance Costs*** (see page 119 in Health, page 172 in Care and page 226 in Being Active)
- ***Investment, Installation and De-installation Costs*** (see page 122 in Health, page 175 in Care and page 229 in Being Active)

Data Protection & Ethical Issues in Cyprus

As Cyprus is at an early stage regarding the implementation and use of new health and care products and services linked to information and communication technologies (ICT), only few information concerning data protection and ethical issues is available in English, though a Law on eHealth 59(I)/2019, as well as an eHealth authority, exists.

Please note the following non-reactive instruments for which **Data Protection & Ethical Issues** are of great importance:

- ***Consideration of Ethical Guidelines*** (see page 94 in Health, page 147 in Care and page 201 in Being Active)
- ***State of Health*** (see page 98 in Health, page 151 in Care and page 205 in Being Active)
- ***Active/Passive Usage*** (see page 103 in Health, page 156 in Care and page 210 in Being Active)
- ***Error Data*** (see page 106 in Health, page 159 in Care and page 213 in Being Active)

Health Technology Assessment:
The government is currently building up its HTA capacity. It is primarily used for pharmaceuticals now (European Commission 2019a).

1.4. Hungary

Hungary applies a Bismarckian insurance model: the main feature is the right to benefits in exchange for contributions. The health system is "in transition" (European Commission 2019a; Lupiañez-Villanueva et al. 2018).

Health & Care Provision in Hungary

The central government is responsible for providing health and care and social care organizations of national scope, whether regional governments are responsible for providing secondary health care providers. The main principle is territorial responsibility, where municipalities are in charge of primary care and county governments decide about specialist health care services. Nevertheless, the responsibility for secondary and tertiary care splits up among different levels of local and regional government. The state owns large multi-specialty county hospitals providing secondary and tertiary inpatient and outpatient care to the acutely and chronically ill (Gaál et al. 2011).

The social care system has three main types of services: home care, daycare, and residential care. However, the eHealth initiative is entirely under the central government via the Ministry of Health, Family, and Social Affairs. Long-term (LTC) and care services are provided either by the health care system or by the social care system, which federal and local governments provide (Hammerschmid et al. 2018; European Commission 2019a; Gaál et al. 2011).

Covid-19 pandemic had a significant impact on adopting new technologies like telemedicine. Services are defined as specific health services provided without personal consultation and sharing of health data via encrypted communication, like diagnosis and therapeutic advice, consultation, referrals to for further examinations by specialists, patient management tasks, care services, providing therapy and rehabilitation, and prescribing medicaments and devices (European Commission 2019a; Lupiañez-Villanueva et al. 2018; Kovecses 2020; Gaál et al. 2011).

Please note the following non-reactive instruments for which **Health & Care provision** is of great importance:

- ***Costs and Revenues during Development and Market Launch*** (see 115 in Health, page 168 in Care and page 222 in Being Active)
- ***Market Potential*** (see page 124 in Health, page 177 in Care and page 231 in Being Active)
- ***Avoided Resource Requirements*** (see page 128 in Health, page 181 in Care and page **Fehler! Textmarke nicht definiert.** in Being Active)
- ***Economic Potential from Increased Labour Market Participation and Voluntary Activity*** (see page 235 in Being Active)

Financing & Reimbursement in Hungary

In 2019, healthcare is predominantly financed through government schemes (8.6 %) and compulsory contributory health care financing schemes (59.8 %), with an additional 28.2 % from out-of-pocket payments (OOP). Most public funding comes from the social health insurance schemes, while the contribution of voluntary health insurance (VHI) is 3.5 % (Eurostat 2021b).

General Practitioners (GPs) are paid based on their employment scheme, whether hospitals are financed and supported by their owners, the share of the state budget, and other income flows. National Electronic Health Record (EHR) System is being under process of development and establishment.

Though there was limited usage of information and communication (ICT) technologies in providing and organizing health and care in the past, the Covid-19 pandemic had a significant impact on adopting new technologies. Up to new legal amendments, contributory health care financing schemes reimburse telemedicine services by using the new set of fiscal codes (European Commission 2019a; Lupiañez-Villanueva et al. 2018; Kovecses 2020; Gaál et al. 2011; T-Systems Hungary n.d.).

Please note the following non-reactive instruments for which **Financing & Reimbursement** is of great importance:

- ***Human Assistance Costs*** (see page 110 in Health, page 163 in Care and page 217 in Being Active)
- ***Financial Burden for Users*** (see page 112 in Health, page 165 in Care and page 219 in Being Active)
- ***Operating Materials and Maintenance Costs*** (see page 119 in Health, page 172 in Care and page 226 in Being Active)
- ***Investment, Installation and De-installation Costs*** (see page 122 in Health, page 175 in Care and page 229 in Being Active)

Data Protection & Ethical Issues in Hungary

As a result of the Covid 19 pandemic, specific legal requirements for telemedicine services have been adapted to include remote services such as remote contact between patient and physician, care, consultation, reminder, intervention, monitoring, and remote referral. The recent amendment aims to clarify the obligations when providing telemedicine services. Specific amendments and duties for health care providers are: (1) Providing necessary equipment (e.g. telecommunication, medical and special equipment for health care services). (2) Establishing and providing rules of procedure and patient information for the usage of telemedicine (e.g. healthcare providers bear the responsibility for patient identification). (3) Providing services via the internet requires a stable and secure connection, including data security, virus protection,

and protection from malicious software. These legal amendments enable providers to offer certain services, such as telemedicine, and to actively procure and create infrastructure co-funded by the government, also supporting developments in this area and probably leading to an increased application of innovative technologies (Kovecses 2020).

Please note the following non-reactive instruments for which **Data Protection & Ethical Issues** are of great importance:

- ***Consideration of Ethical Guidelines*** (see page 94 in Health, page 147 in Care and page 201 in Being Active)
- ***State of Health*** (see page 98 in Health, page 151 in Care and page 205 in Being Active)
- ***Active/Passive Usage*** (see page 103 in Health, page 156 in Care and page 210 in Being Active)
- ***Error Data*** (see page 106 in Health, page 159 in Care and page 213 in Being Active)

Health Technology Assessment:
Further measures to improve quality will include implementing a monitoring and evaluation system based on defined indicators. In addition, major IT development plans include establishing a database for the insurance system, developing a personal identification system, improving remote diagnostics and telemedicine (European Commission 2019a). Regarding supporting the decision-making process with sound cost/effectiveness data and good quality economic studies, an English guideline for health technology assessment was published in 2017 by Szende et al. 2017).

1.5. Italy

The Italian National Health System (NHS) follows a model similar to the Beveridge model. Therefore, taxes finance health and care coverage for the Italian population to a large extent (Nuti et al. 2012).

Health & Care Provision in Italy

According to the organizational setting of the Italian Health Care System, the Ministry of Health, in agreement with the Ministry of Economy and Finance, defines general objectives and national policy priorities and the basic levels of health care treatments provided for free over the national territory. Health and care systems are regionally organized based on the NHS. Regions provide primary, specialist outpatient, and hospital care, health promotion, disease prevention and rehabilitation, long-term nursing, and psychiatric care (European Commission 2019a; Ferré et al. 2014; Tediosi & Gabriele 2010).

The regions and local governments provide long-term care and social care services. Informal carers provide caregiving to a large extent. This situation occurs in regions where public services are less advanced and in families who cannot afford private services. Regions are in charge of the health component of LTC via local health authorities. The social component of LTC services includes a heterogeneous group of benefits, largely in kind, mainly provided at a local level by municipalities, directly, or in an association. Stakeholders directly involved in organizing LTC services are municipalities, local health authorities, nursing homes, and the National Institute of Social Security (European Commission 2019a; Tediosi & Gabriele 2010).

The central government promotes eHealth initiatives. Current developments focus on increasing online services, electronic health records (EHRs), and the digitalization of medical prescriptions and certificates (Hammerschmid et al. 2018; European Commission 2019a; Ferré et al. 2014; Lupiañez-Villanueva et al. 2018).

Please note the following non-reactive instruments for which **Health & Care provision** is of great importance:

- ***Costs and Revenues during Development and Market Launch*** (see 115 in Health, page 168 in Care and page 222 in Being Active)
- ***Market Potential*** (see page 124 in Health, page 177 in Care and page 231 in Being Active)
- ***Avoided Resource Requirements*** (see page 128 in Health, page 181 in Care and page **Fehler! Textmarke nicht definiert.** in Being Active)
- ***Economic Potential from Increased Labour Market Participation and Voluntary Activity*** (see page 235 in Being Active)

Financing & Reimbursement in Italy

In 2019, healthcare predominantly finances through government schemes (73.8 %), while compulsory contributory health care financing schemes only account for 0.2 %, with an additional 23.3 % from out-of-pocket payments (OOP). Most public funding comes from government spending, while the contribution of voluntary health insurance (VHI) is 2.8 % (Eurostat 2021b).

Taxes finance health and care largely: national and regional taxes, supplemented by co-payments for pharmaceuticals and outpatient care. A regionally-based NHS is in charge of the central government and the regional governments to allocate the funds. Central government, provinces, and regions organize the funding of LTC services (Ferré et al. 2014).

Please note the following non-reactive instruments for which **Financing & Reimbursement** is of great importance:

- ***Human Assistance Costs*** (see page 110 in Health, page 163 in Care and page 217 in Being Active)
- ***Financial Burden for Users*** (see page 112 in Health, page 165 in Care and page 219 in Being Active)
- ***Operating Materials and Maintenance Costs*** (see page 119 in Health, page 172 in Care and page 226 in Being Active)
- ***Investment, Installation and De-installation Costs*** (see page 122 in Health, page 175 in Care and page 229 in Being Active)

Data Protection & Ethical Issues in Italy

Following the General Data Protection Regulation (GDPR), data processing purposes must be specific, explicit, and legitimate. Privacy information clearly indicates the subject's rights, such as accessibility, correction or cancellation, limitation of processing personal data to data portability, withdrawal consent, and complaint with a supervisory authority. The main issues concern the large amount of data generated, the liability of subjects involved in their creation and user privacy protection, and correct usage of personal data collected. Other issues relate to the circulation of health data, outsourcing, and delocalization of systems and services, and storing in geographic locations are often regulated by different legislation (Selletti et al. 2021).

Please note the following non-reactive instruments for which **Data Protection & Ethical Issues** are of great importance:

- ***Consideration of Ethical Guidelines*** (see page 94 in Health, page 147 in Care and page 201 in Being Active)
- ***State of Health*** (see page 98 in Health, page 151 in Care and page 205 in Being Active)
- ***Active/Passive Usage*** (see page 103 in Health, page 156 in Care and page 210 in Being Active)
- ***Error Data*** (see page 106 in Health, page 159 in Care and page 213 in Being Active)

Health Technology Assessment:
Health Technology Assessment is undertaken at various levels, although no national structure is responsible for conducting, promoting, coordinating, or financing HTA. Clinical guidelines for medical interventions and medicines are established through the National Programme on Clinical Guidelines (European Commission 2019a; Gorkavenko et al. 2019).

1.6. Luxembourg

Luxembourg applies a Bismarck health and care system model based on general and compulsory social insurance (Ministerio de Sanidad 2019; Lupiañez-Villanueva et al. 2018).

Health & Care Provision in Luxembourg

The Ministry of Social Security supervises the public institutions funding health care, sickness leave, and long-term care, while the Ministry of Family Affairs oversees long-term care facilities, home care networks, and care services for disabled people (OECD 2019).

General practitioners (GPs) primarily working in private practices offer primary health services. The state system covers the majority of treatments provided by GPs and specialists as well as laboratory tests, pregnancy, childbirth, rehabilitation, prescriptions, and hospitalization (European Commission 2019a; HealthManagement 2010).

Organizing care splits up two entities. National Health Insurance manages the budget for LTC services and decides about the care needed by LTC beneficiaries. The State Office for Assessment and Monitoring of long-term care insurance assess daily living activities and other long-term care services and designs care plans (European Commission 2019a). The long-term care law defines itself by four principles: priority to home care, priority to benefits-in-kind, priority to rehabilitation and prevention measures, and continuity of long-term caregiving (European Commission 2019a; OECD 2019).

Many eHealth initiatives and projects are developed and performed. Efforts like the national eHealth plan and digital initiatives are ongoing (Hammerschmid et al. 2018; European Commission 2019a; OECD 2019; Lupiañez-Villanueva et al. 2018).

Please note the following non-reactive instruments for which **Health & Care provision** is of great importance:

- ***Costs and Revenues during Development and Market Launch*** (see 115 in Health, page 168 in Care and page 222 in Being Active)
- ***Market Potential*** (see page 124 in Health, page 177 in Care and page 231 in Being Active)
- ***Avoided Resource Requirements*** (see page 128 in Health, page 181 in Care and page **Fehler! Textmarke nicht definiert.** in Being Active)
- ***Economic Potential from Increased Labour Market Participation and Voluntary Activity*** (see page 235 in Being Active)

Financing & Reimbursement in Luxembourg

In 2019, healthcare is predominantly financed through compulsory contributory health care financing schemes (80.3 %) and government schemes (4.7 %), with an additional 9.6 % from out-of-pocket payments (OOP). Most public funding comes from the social health insurance schemes, while the contribution of voluntary health insurance (VHI) is 4.1 % (Eurostat 2021b).

The central government finances the healthcare system via the national insurance system. Social insurance contributions equally split between employers and employees fund the public health and care system. The Ministries of Health and Social Security are the leading institutions regulating and deciding on the health system's funding (Hammerschmid et al. 2018; European Commission 2019a; OECD 2019; Lupiañez-Villanueva et al. 2018).

Please note the following non-reactive instruments for which **Financing & Reimbursement** is of great importance:

- ***Human Assistance Costs*** (see page 110 in Health, page 163 in Care and page 217 in Being Active)
- ***Financial Burden for Users*** (see page 112 in Health, page 165 in Care and page 219 in Being Active)
- ***Operating Materials and Maintenance Costs*** (see page 119 in Health, page 172 in Care and page 226 in Being Active)
- ***Investment, Installation and De-installation Costs*** (see page 122 in Health, page 175 in Care and page 229 in Being Active)

Data Protection & Ethical Issues in Luxembourg

In accordance with General Data Protection Regulation (GDPR), patients have the rights to access, to rectification, to erasure, right to restriction of processing, to object, to data portability, to request receipt of personal data in a structured and commonly machine-readable format (Luxembourg Institute of Health 2018).

The research identified several issues and problems for the patients: Lack of access or difficulty to use new technologies (e.g., Internet), so the technology is not available for everybody. Loss of privacy if the information is shared inappropriately. Lack of clarity about patient summary management and data consistency responsibilities (Pruski et al. 2010).

Please note the following non-reactive instruments for which **Data Protection & Ethical Issues** are of great importance:

- ***Consideration of Ethical Guidelines*** (see page 94 in Health, page 147 in Care and page 201 in Being Active)
- ***State of Health*** (see page 98 in Health, page 151 in Care and page 205 in Being Active)
- ***Active/Passive Usage*** (see page 103 in Health, page 156 in Care and page 210 in Being Active)
- ***Error Data*** (see page 106 in Health, page 159 in Care and page 213 in Being Active)

Health Technology Assessment:
The use of Health Technology Assessment appears to be limited in terms of the definition of the benefit basket (European Commission 2019a).

1.7. Netherlands

The Netherlands has a Bismarck model health system based on general and compulsory social insurance (Ministerio de Sanidad 2019).

Health & Care Provision in the Netherlands

The organization and structure of public health services is a shared responsibility between the national and local government (and its approx. 400 municipalities). The federal government has the overall responsibility (regulation, funding, supervision, international collaboration, etc.), whereas municipalities manage the operative implementation of public health and care services. Besides the governmental collaboration, a cross-sectoral approach between public and private sectors is also applied as policy decisions result from collective decision-making (together with private industries, schools, employers, sports organizations, etc.). The international level is also relevant, especially concerning global challenges such as viruses and food safety (Kroneman et al. 2016; Maarse et al. 2018).

Independent general practitioners (GPs) are in charge of primary health care, often working in private group practices. GPs act as gatekeepers which means that patients have to see a primary care provider deciding whether specialist services (e.g., cardiologists) are necessary. Almost all hospitals are private but not for profit.

Local authorities provide care and the needs assessment while municipalities organize caring services and help for domestic activities (European Commission 2019a). Special long-term care administrators administer the Long-Term Care Act at the behest of the central government. Additionally, several other organizations are involved in its implementation, such as the Care Assessment Agency and the Central Administration Office (European Commission 2019a; Central administration Office; Ministerie van Volksgezondheid, Welzijn en Sport, 2020).

There is no national system for data exchange on ePrescription or electronic health records (EHR). Data exchange is facilitated primarily on a regional level (European Commission, 2019). The Dutch government actively stimulated and supported the development and adoption of health technology and digitalization through task forces and subsidized innovation programs, knowledge platforms, and events targeting innovators and health providers (Dutch Ministry of Foreign Affairs 2021).

Please note the following non-reactive instruments for which **Health & Care provision** is of great importance:

- ***Costs and Revenues during Development and Market Launch*** (see 115 in Health, page 168 in Care and page 222 in Being Active)
- ***Market Potential*** (see page 124 in Health, page 177 in Care and page 231 in Being Active)
- ***Avoided Resource Requirements*** (see page 128 in Health, page 181 in Care and page **Fehler! Textmarke nicht definiert.** in Being Active)
- ***Economic Potential from Increased Labour Market Participation and Voluntary Activity*** (see page 235 in Being Active)

Financing & Reimbursement in the Netherlands

In 2019, healthcare is predominantly financed through compulsory contributory health care financing schemes (76.2 %) and government schemes (6.5 %), with an additional 10.6 % from out-of-pocket payments (OOP). Most public funding comes from the social health insurance schemes, while the contribution of voluntary health insurance (VHI) is 6.8 % (Eurostat 2021b).

Funding for health is partially regulated on the government level with publicly regulated/private insurance schemes through grants (Hammerschmid et al. 2018). The statuary health insurance is funded by different sources like taxes on income from employees (50 %), a state contribution (50 %) or the insured under the age of 18, nominal premium, and deductible (European Commission 2019a).

In 2021 the Dutch Healthcare Authority is increasing funding for eHealth. Telehealth costs, e.g., an online consultation via video communication, can be reimbursed the same way as face-to-face healthcare services by a (GP) or a specialist (e.g., internist; Ministerie van Algemene Zaken 2021).

Please note the following non-reactive instruments for which **Financing & Reimbursement** is of great importance:

- ***Human Assistance Costs*** (see page 110 in Health, page 163 in Care and page 217 in Being Active)
- ***Financial Burden for Users*** (see page 112 in Health, page 165 in Care and page 219 in Being Active)
- ***Operating Materials and Maintenance Costs*** (see page 119 in Health, page 172 in Care and page 226 in Being Active)
- ***Investment, Installation and De-installation Costs*** (see page 122 in Health, page 175 in Care and page 229 in Being Active)

Data Protection & Ethical Issues in the Netherlands

As there is no general framework concerning the provision of health and care services by applying information and communication technologies (ICT), various laws are applied regarding regulation.

Implementation of the General Data Protection Regulation (GDPR) ensures rights and rules regarding data protection and privacy in the healthcare sector. These regulations relate to the electronic processing of data, patient data, necessary security standards as encryption, and large-scale processing. Healthcare has to comply with the legislation, otherwise risking a fine (Bos 2021).

Please note the following non-reactive instruments for which **Data Protection & Ethical Issues** are of great importance:

- ***Consideration of Ethical Guidelines*** (see page 94 in Health, page 147 in Care and page 201 in Being Active)
- ***State of Health*** (see page 98 in Health, page 151 in Care and page 205 in Being Active)
- ***Active/Passive Usage*** (see page 103 in Health, page 156 in Care and page 210 in Being Active)
- ***Error Data*** (see page 106 in Health, page 159 in Care and page 213 in Being Active)

Health Technology Assessment:

The National Institute for Health Research and the Health Care Insurance Board conduct and gather information on health technology assessment (HTA). Based on this HTA, the Health Care Insurance Board advises the central government on what should be covered under the basic benefit package of care and the extent of reimbursement /cost-sharing in the system. New treatments or methods of diagnosis-setting adopted by medical specialists are more or less automatically covered in the basic package since the basic package covers health care "according to the latest developments in science and technology" (European Commission 2019a). The latest guidelines for conducting economic evaluation in the fields of health and care were published in 2016 (ZiNL 2016).

1.8. Norway

The Norwegian National Health System (NHS) follows a model similar to the Beveridge model. Primarily taxes finance health and care supply for the Norwegian population provided by the government (Lupiañez-Villanueva et al. 2018).

Health & Care Provision in Norway

Norway has a universal, nationalized system. The system is semi-decentralized, resulting in health and care provided on three levels: national, regional health authorities, and municipalities. The central government is responsible for specialist care delivered via four regional health authorities; municipalities are responsible for primary care and, increasingly, for other types of care. The overall responsibility for public health rests with the Ministry of Health and Care Services, while the municipalities are responsible for implementing cross-sectoral public health interventions locally. Municipalities are responsible for providing and financing primary care, including rehabilitation, physiotherapy and nursing, and after-hours emergency services. Mainly self-employed physicians offer it as part of municipal service (Sperre Saunes et al. 2020).

General Practitioners act as gatekeepers meaning patients have to see a primary care provider who decides whether treatment by a specialist is necessary (e.g., cardiologist). The Ministry of Health and Care Services has direct responsibility for offering services by specialists. Hospitals provide inpatient and outpatient specialized care (Sperre Saunes et al. 2020).

The organization and provision of long-term care are the municipalities' sole responsibility and are often administratively integrated with other health and social services at the local level. None of the LTC settings is reserved explicitly for the elderly. Long-term care has three types: patients' homes, nursing homes, or sheltered homes run by the municipalities. Except for home care, long-term care in municipal settings requires substantial co-payments by users (Sperre Saunes et al. 2020).

The Ministry of Health and Care Services owns the Norwegian Health Net trust, responsible for providing a secure electronic exchange of patient information via a health communication network between all relevant parties within the health and social services sectors. The Directorate of e-Health within the ministry has the overall responsibility for digitalizing the health and care sector. In addition, the Norwegian Directorate for eHealth is responsible for the governance of the eHealth system. In contrast, the Norwegian Health Network, covering most providers, has recently implemented significant eHealth developments (Sperre Saunes et al. 2020).

Please note the following non-reactive instruments for which **Health & Care provision** is of great importance:

- ***Costs and Revenues during Development and Market Launch*** (see 115 in Health, page 168 in Care and page 222 in Being Active)
- ***Market Potential*** (see page 124 in Health, page 177 in Care and page 231 in Being Active)
- ***Avoided Resource Requirements*** (see page 128 in Health, page 181 in Care and page **Fehler! Textmarke nicht definiert.** in Being Active)
- ***Economic Potential from Increased Labour Market Participation and Voluntary Activity*** (see page 235 in Being Active)

Financing & Reimbursement in Norway

Norway has universal health coverage, funded primarily by general taxes and by payroll contributions shared by employers and employees. Government schemes accounted for 85.8 %, out-of-pocket payments (OOP) for 13.9 % and voluntary health insurance (VHI) for 0.3 % in 2019 (Eurostat 2021b). The Parliament is responsible for the Ministry of Health and Care Services, which govern the health system through four regional health authorities, providing them with finances. These authorities manage their region's ICT investments in clinical and administrative systems. eHealth and innovation projects are financially supported by Innovation Norway and the directorate of health (Vestli 2018; Grisot et al. 2017; Doup et al. 2010; Tikkanen et al. 2020; Lupiañez-Villanueva et al. 2018).

Please note the following non-reactive instruments for which **Financing & Reimbursement** is of great importance:

- ***Human Assistance Costs*** (see page 110 in Health, page 163 in Care and page 217 in Being Active)
- ***Financial Burden for Users*** (see page 112 in Health, page 165 in Care and page 219 in Being Active)
- ***Operating Materials and Maintenance Costs*** (see page 119 in Health, page 172 in Care and page 226 in Being Active)
- ***Investment, Installation and De-installation Costs*** (see page 122 in Health, page 175 in Care and page 229 in Being Active)

Data Protection & Ethical Issues in Norway

According to the Health Personnel Act, healthcare staff obliges to confidentiality and must prevent others from gaining access to data about health or illness or any other personal condition with which they come into contact due to their work. It is also illegal to read, search, obtain, use, or acquire the health mentioned above data in any other way unless it is to provide health and care services to the individual, administer such treatment, or there is a specific legal basis in law or regulations.(Weitzenboeck & Coll 2018).

All common ethical issues are closely connected to the quality of the services. Common ethical issues: patient autonomy; decision-making competence, quality, and competence in the service; confidentiality (Morten et al. 2016); these shortcomings apply to eHealth solutions as well. Accessibility to digital health products and services is another issue. Not everybody from vulnerable groups has a technological background (smartphone, computer, knowledge, skills, etc.) to use solutions derived from information and communication technologies. On the other side, mental health patients may not wish to use a service requiring an application on their smartphone, which also causes ethical issues. Home care customers using video links may also think that they are being spied upon. In fact, in general, it can be challenging to guarantee home care customers' security while still preserving their privacy (Lundgren et al. 2020).

Please note the following non-reactive instruments for which **Data Protection & Ethical Issues** are of great importance:

- ***Consideration of Ethical Guidelines*** (see page 94 in Health, page 147 in Care and page 201 in Being Active)
- ***State of Health*** (see page 98 in Health, page 151 in Care and page 205 in Being Active)
- ***Active/Passive Usage*** (see page 103 in Health, page 156 in Care and page 210 in Being Active)
- ***Error Data*** (see page 106 in Health, page 159 in Care and page 213 in Being Active)

Health Technology Assessment:

The purpose of health technology assessment is (1) improving patient safety connected to the introduction of new health technologies, (2) ensuring that patients as quickly as possible gain equal access to new health technologies that have been documented as being effective and fulfill requirements concerning safety and are cost-effective, (3) ensuring that new health technologies that are ineffective and/or harmful for patients are not introduced, and those old health technologies are disinvested, (4) providing an appropriate decision-making platform for priority setting within the specialist health service based on HTA, (5) ensuring rational use of resources within specialist health care, and (6) implementing a predictable and systematic process for introducing new health technologies (Hansen et al. 2017). The latest guidelines for conducting health technology assessments were published in 2012 (Norwegian Medicines Agency 2012).

1.9. Poland

The Polish health and care system went from a centralized system based on the Semashko model to a decentralized system of compulsory health insurance in 1999, i.e., a Bismarck model. However, the Polish design is still “in transition” (Kautsch et al. 2016; European Commission 2019a).

Health & Care Provision in Poland

The central government is responsible for the legislation, regulation, funding, and provision of health and social welfare (Hammerschmid et al. 2018). The governance of the health and care system splits up between the Ministry of Health) and three levels of territorial self-government (Sowada et al. 2019).

Public and non-public therapeutic entities and private medical practitioners provide health services with the National Health Fund remaining the sole purchaser in the statutory health care insurance system. Similar to other countries, general practitioners (GPs) act as gatekeepers. Most hospitals and ambulatory services are public and operate as independent public health care units, and certain shortcomings of their legal form resulted in poor financial management. The Minister of Health is the founder of specialist hospitals and medical colleges and has a supervisory role. The territorial self-governments own most public hospitals. The type of owner roughly corresponds to the complexity of provided services, with county hospitals providing less complex care than provincial hospitals (European Commission 2019a; Sowada et al. 2019).

There is no explicit and separate scheme with long-term care (LTC). Instead, the provision of LTC is fragmented and governed by several laws relating to healthcare, social care, family benefits (nursing benefits and nursing allowance), pensions, and rehabilitation. The coverage by formal LTC is low, and traditionally family members are in charge of LTC, i.e., informal caregiving. Available types of legal care are cash benefits and in-kind benefits (Sowada et al. 2019; European Commission 2019a).

Centre for Health Information Systems is implementing IT solutions in the health system. In addition, a new strategic document in eHealth is currently under development as a part of a more comprehensive strategy of IT development in public institutions in Poland coordinated by the Ministry of Digital Affairs (Sowada et al. 2019).

Please note the following non-reactive instruments for which **Health & Care provision** is of great importance:

- ***Costs and Revenues during Development and Market Launch*** (see 115 in Health, page 168 in Care and page 222 in Being Active)
- ***Market Potential*** (see page 124 in Health, page 177 in Care and page 231 in Being Active)
- ***Avoided Resource Requirements*** (see page 128 in Health, page 181 in Care and page **Fehler! Textmarke nicht definiert.** in Being Active)
- ***Economic Potential from Increased Labour Market Participation and Voluntary Activity*** (see page 235 in Being Active)

Financing & Reimbursement in Poland

In 2019, healthcare is predominantly financed through compulsory contributory health care financing schemes (61.8 %) and government schemes (9.9 %), with an additional 13.9 % from out-of-pocket payments (OOP). Most public funding comes from the social health insurance schemes, while the contribution of voluntary health insurance (VHI) is at a very low level (0.3 %; Eurostat 2021b).

The Polish health and care system's financing splits between the Ministry of Health, the National Health Fund, and local governments. eHealth development in the EU Member States' public sector is driven by European targets, determining national legislation (Kautsch et al. 2016).

Please note the following non-reactive instruments for which **Financing & Reimbursement** is of great importance:

- ***Human Assistance Costs*** (see page 110 in Health, page 163 in Care and page 217 in Being Active)
- ***Financial Burden for Users*** (see page 112 in Health, page 165 in Care and page 219 in Being Active)
- ***Operating Materials and Maintenance Costs*** (see page 119 in Health, page 172 in Care and page 226 in Being Active)
- ***Investment, Installation and De-installation Costs*** (see page 122 in Health, page 175 in Care and page 229 in Being Active)

Data Protection & Ethical Issues in Poland

According to the Act on Patient Rights and Patient Ombudsman, medical documentation research needs patients' consent. Documentation in an anonymized form may be transferred to a scientific institution without obtaining such consent (European Commission 2019a; Kowalczuk-Pakula et al. 2021).

The issue of basic infrastructure such as computers, servers, the Internet connection was brought up repeatedly by all groups. It is quoted as the biggest obstacle (apart from the legal ones) to implementing even essential eHealth solutions. Concluding there is limited infrastructure and legal basis for eHealth in Poland to start a discussion on ethical issues of its solutions (Kautsch et al. 2016).

Please note the following non-reactive instruments for which **Data Protection & Ethical Issues** are of great importance:

- ***Consideration of Ethical Guidelines*** (see page 94 in Health, page 147 in Care and page 201 in Being Active)
- ***State of Health*** (see page 98 in Health, page 151 in Care and page 205 in Being Active)
- ***Active/Passive Usage*** (see page 103 in Health, page 156 in Care and page 210 in Being Active)
- ***Error Data*** (see page 106 in Health, page 159 in Care and page 213 in Being Active)

Health Technology Assessment:

The Centre for Health Care Quality Monitoring provides independent accreditation based on a published set of standards. The use of technology assessment is increasing, leading to evidence-based contracting of services. The Agency for Health Technology Assessment and Tariff System was established in 2005 as an advisory body to the Ministry of Health (European Commission, 2019). The latest guidelines for conducting health technology assessments were published in 2009 (Agency for Health Technology Assessment 2009).

1.10. Portugal

The Portuguese National Health System (NHS) follows a model similar to the Beveridge model. The government provides health and care coverage for the Portuguese population predominantly financed by taxes (Lupiañez-Villanueva et al. 2018; Ministerio de Sanidad 2019; European Commission 2019a).

Health & Care Provision in Portugal

The central government and local governments share responsibility and have competencies in providing health and social welfare (Hammerschmid et al. 2018). The Central Administration of the Health System implements the decisions of the Ministry of Health under its supervision. It coordinates, monitors, and controls NHS resource allocation and use, human resources policies, and health facilities management. In addition, this institution defines the budget allocation across regions and areas of provision. The Ministry of Health sets the national health policy strategy, defining public health and policy priorities, specifying the regulatory framework, describing the system organogram, and providing the overall management of the health and care system. Five regional health authorities are responsible for implementing public health objectives and purchasing primary, specialist, and hospital care for their respective catchment population under the framework defined by the Central Administration of the Health System.

NHS (National Health Service) supplies primary health services (including family medicine, pre-natal and post-natal follow-up, prevention and promotion), outpatient specialist consultations, and hospital care (day-case and inpatient) directly through a network of publicly owned facilities (European Commission 2019a). In this regard, general practitioners (GPs) act as gatekeepers, though patients often bypass their GP by visiting emergency departments (Simões et al. 2017).

Public long-term care is provided through residential structures for elderly people and a long-term care network managed and supervised by the Ministry of Labour, Solidarity and Social Security (European Commission 2019a). The network provides post-acute health and social assistance for dependent persons (referred by hospitals and health primary care units). Other types of care are convalescence care, post-acute rehabilitation services, medium and long-term care, and home care (European Commission 2019a).

Cooperating with Shared Services of the Ministry of Health, the Central Administration of the Health System develops information systems supporting monitoring, assessment and policy implementation. They have introduced several eHealth actions, including the individual electronic NHS card, ePrescription, eAppointments, and electronic health records (EHR; European Commission, 2019).

Please note the following non-reactive instruments for which **Health & Care provision** is of great importance:

- ***Costs and Revenues during Development and Market Launch*** (see 115 in Health, page 168 in Care and page 222 in Being Active)
- ***Market Potential*** (see page 124 in Health, page 177 in Care and page 231 in Being Active)
- ***Avoided Resource Requirements*** (see page 128 in Health, page 181 in Care and page **Fehler! Textmarke nicht definiert.** in Being Active)
- ***Economic Potential from Increased Labour Market Participation and Voluntary Activity*** (see page 235 in Being Active)

Financing & Reimbursement in Portugal

In 2019, healthcare is predominantly financed through government schemes (58.6 %) and compulsory contributory health care financing schemes (2.4 %), with an additional 30.5 % from out-of-pocket payments (OOP). Most public funding comes from government schemes, while the contribution of voluntary health insurance (VHI) is at 8.6 % (Eurostat 2021b).

The budget for publicly funded health and care services is defined annually in parliament when the general budget is approved. General taxation is the leading financier of the NHS. The Ministry of Health receives a global budget for the NHS from the Ministry of Finance, which is then allocated to several institutions within the NHS. NHS provides 100 % population coverage to all the residents and Portuguese citizens.

Please note the following non-reactive instruments for which **Financing & Reimbursement** is of great importance:

- ***Human Assistance Costs*** (see page 110 in Health, page 163 in Care and page 217 in Being Active)
- ***Financial Burden for Users*** (see page 112 in Health, page 165 in Care and page 219 in Being Active)
- ***Operating Materials and Maintenance Costs*** (see page 119 in Health, page 172 in Care and page 226 in Being Active)
- ***Investment, Installation and De-installation Costs*** (see page 122 in Health, page 175 in Care and page 229 in Being Active)

Data Protection & Ethical Issues in Portugal

The Act on the Protection of Personal Data defines the statute and the regime of personal genetic and health information, forming the main legal framework of health data. Following this personal health information as any kind of information directly or indirectly related to health, present or future, of a person, whether alive or dead, as well as his or her medical and family history (Gonçalves et al. 2017).

Transparency requires the controller to provide data subjects with details of the following in advance of the data processing as the purposes of the processing, the controller's identity and address, the data subjects' rights to access their data (Madureira 2021).

The Regulation of Medical Ethics extensively regulates the use of telemedicine services. Following the Portuguese Medical Association, some aspects should be kept in mind when considering telemedicine services, such as the respect for the patient-doctor relationship, the independence of the doctor's opinion, and confidentiality and mutual confidence (Macedo 2021).

Please note the following non-reactive instruments for which **Data Protection & Ethical Issues** are of great importance:

- ***Consideration of Ethical Guidelines*** (see page 94 in Health, page 147 in Care and page 201 in Being Active)
- ***State of Health*** (see page 98 in Health, page 151 in Care and page 205 in Being Active)
- ***Active/Passive Usage*** (see page 103 in Health, page 156 in Care and page 210 in Being Active)
- ***Error Data*** (see page 106 in Health, page 159 in Care and page 213 in Being Active)

Health Technology Assessment:

The National Authority of Medicines and Health Products, the national HTA organization of Portugal, uses HTA for reimbursement and benefit packages purposes. Moreover, HTA primarily assesses pharmaceuticals' market and reimbursement of patients' access to medicines (European Commission 2019a; Pinto et al. 2000).

1.11. Romania

Romania applies a Bismarckian insurance model: the main feature is the right to benefits in exchange for contributions. The health system is currently "in transition" (European Commission 2019a; Ministerio de Sanidad 2019; Lupiañez-Villanueva et al. 2018).

Health & Care Provision in Romania

The provision is a responsibility of the central government, provincial, and regional governments. The leading central institutions in charge are the Ministry of Public Health and the National Health Insurance House, regulating and administering mandatory health insurance, negotiating contracts with physicians, and evolving remuneration systems (Vladescu et al. 2016).

General Practitioners act as gatekeepers, though some patients still bypass it. Ambulatory specialist care is available in specialized centers and hospital outpatient departments. District Health Insurance Funds purchase and reimburse care for their respective population by establishing contracts with care providers. Inpatient care is provided in predominantly publicly-owned hospitals (European Commision 2019; Hammerschmid et al. 2018).

Long-term care is fragmented and governed by healthcare, social assistance, pensions, and rehabilitation laws causing informal caregiving. There are three types of care and community services: temporary or permanent home care, temporary or permanent care in a residential center, and care in daily centers (European Commission 2019a).

An electronic health record (EHR) implementation took place in 2014. To some extent, primary care switched to telehealth/-medicine during the Covid-19 pandemic supported by general practitioners (GPs; European Commission 2019a; Florea et al. 2021).

Please note the following non-reactive instruments for which **Health & Care provision** is of great importance:

- ***Costs and Revenues during Development and Market Launch*** (see 115 in Health, page 168 in Care and page 222 in Being Active)
- ***Market Potential*** (see page 124 in Health, page 177 in Care and page 231 in Being Active)
- ***Avoided Resource Requirements*** (see page 128 in Health, page 181 in Care and page **Fehler! Textmarke nicht definiert.** in Being Active)
- ***Economic Potential from Increased Labour Market Participation and Voluntary Activity*** (see page 235 in Being Active)

Financing & Reimbursement in Romania

In 2019, healthcare is predominantly financed through compulsory contributory health care financing schemes (65.0 %) and government schemes (15.4 %), with an additional 18.9 % from out-of-pocket payments (OOP). Most public funding comes from the social health insurance schemes, while the contribution of voluntary health insurance (VHI) is at a very low level (0.7 %; Eurostat 2021b).

Central, federal, and local governments finance the health and care system via compulsory social security contributions. The National Health Insurance House is the primary financial source of the system receiving grants charged by the National Agency for Fiscal Administration. Social health insurance is compulsory; tax revenues finance health promotion, disease prevention activities, and capital investment. EU also provided some funding for e-health/IT projects (European Commission 2019a; Ministerio de Sanidad 2019; Lupiañez-Villanueva et al. 2018; Hammerschmid et al. 2018).

Please note the following non-reactive instruments for which **Financing & Reimbursement** is of great importance:

- ***Human Assistance Costs*** (see page 110 in Health, page 163 in Care and page 217 in Being Active)
- ***Financial Burden for Users*** (see page 112 in Health, page 165 in Care and page 219 in Being Active)
- ***Operating Materials and Maintenance Costs*** (see page 119 in Health, page 172 in Care and page 226 in Being Active)
- ***Investment, Installation and De-installation Costs*** (see page 122 in Health, page 175 in Care and page 229 in Being Active)

Data Protection & Ethical Issues in Romania

Data Protection Law sets out the general requirements for processing health data. The Data Protection Law governed the collection and the processing of personal data (Alexandru 2018). Health data processing for an automated decision-making purpose or profiling is permitted only with the data subject's explicit consent (Buzescu Ca 2018). Biometric and health data processing because of undertaking an automated decision or for generating profiles shall take place exclusively based on express consent or express legal obligation to implement adequate data privacy measures. Mainly regarding health data, there are no national definitions, and the GDPR definition applies. The Law stipulates that biometric data and health data can be processed on the basis of express legal obligation. This legal basis is also applicable to the processing of national identification numbers. Law 363/2018 states that sensitive data can be processed only if strictly necessary on a case-by-case basis if such processing is expressly provided by law (Timofte & Cretu 2021).

From the research, it is made a conclusion that ethical issues with eHealth considered by Romanian authorities are connected to (1) obtaining informed consent, (2) feeling of safety, (3) vulnerability to the health risk for elderly in case of improper diagnosis and treatment (Bajenaru et al. 2020).

Please note the following non-reactive instruments for which **Data Protection & Ethical Issues** are of great importance:

- ***Consideration of Ethical Guidelines*** (see page 94 in Health, page 147 in Care and page 201 in Being Active)
- ***State of Health*** (see page 98 in Health, page 151 in Care and page 205 in Being Active)
- ***Active/Passive Usage*** (see page 103 in Health, page 156 in Care and page 210 in Being Active)
- ***Error Data*** (see page 106 in Health, page 159 in Care and page 213 in Being Active)

Health Technology Assessment:

An interim Health Technology Assessment (HTA) tool to implement evidence-based access to essential technologies has been implemented in 2015, and reimbursement rates of some medicines without proof of health benefits were reduced to 20 % from the list of compensated drugs, resulting in significant savings (European Commission 2019a).

1.12. Slovenia

Slovenia applies a Bismarckian model: the main feature is the right to benefits in exchange for contributions. The health and care system is currently "in transition" (European Commission 2019a; Lupiañez-Villanueva et al. 2018).

Health & Care Provision in Slovenia

Slovenia has a social health insurance system operationalized as Health Insurance Institute of Slovenia, providing universal compulsory health insurance. The central government is responsible for the legislation, regulation, funding, and provision of health. It provisions tertiary and secondary levels of the health system, whereas local governments are responsible for the primary level (Hammerschmid et al. 2018).

Primary care is provided mainly through a network of community-level primary health care centers owned and managed by municipalities, with general practitioners (GPs) acting as gatekeepers. Specialist outpatient activities at the secondary care level are performed in public and private hospitals, primary healthcare centers, private specialists, and spas. The key regulatory role rests with the Ministry of Health, the owner of all public hospitals and national institutes, their key manager and investor, and the granting authority of practice authorizations for specialists (Albreht et al. 2016).

There is no uniform system regarding care and long-term care (LTC). Instead, different forms of services and benefits, classified as LTC services, are offered by different systems (healthcare, pension, social and parental protection, etc.) and are regulated by various acts from these areas. Long-term care and care overall is the responsibility of the Ministry of Health and the Ministry of Labour, Family, Social Affairs and Equal Opportunities.

The national eHealth project includes different electronic solutions with a strategic goal to increase the quality and efficiency of the health system, including better planning and management of health care organizations and the health system as a whole (European Commission 2019a). The government promotes initiatives for eHealth (Albreht et al. 2016).

The national eHealth project includes different electronic solutions with a strategic goal to increase the quality and efficiency of the health system (European Commission 2019a; Hammerschmid et al. 2018; Lupiañez-Villanueva et al. 2018; Offerman 2016).

Please note the following non-reactive instruments for which **Health & Care provision** is of great importance:

- ***Costs and Revenues during Development and Market Launch*** (see 115 in Health, page 168 in Care and page 222 in Being Active)
- ***Market Potential*** (see page 124 in Health, page 177 in Care and page 231 in Being Active)
- ***Avoided Resource Requirements*** (see page 128 in Health, page 181 in Care and page **Fehler! Textmarke nicht definiert.** in Being Active)
- ***Economic Potential from Increased Labour Market Participation and Voluntary Activity*** (see page 235 in Being Active)

Financing & Reimbursement in Slovenia

Compulsory health insurance contributions (68.6 %) are the major source of health care financing when general national and municipal-level taxation represents only a minor percentage of current health expenditure (only 4.2 % in 2019). Private sources consist of two main sources of financing: out-of-pocket payments (11.7 %) and voluntary health insurance (VHI; 15.6 %; Eurostat 2021b). Compulsory health insurance pays for most health-related risks, but not all of them and neither in full. The balance is either to be paid by the insured person or the insured person signs a contract with a private health insurance company. More than 95 % of the population liable for co-payments is insured by voluntary complementary health insurance (European Commission 2019a; Hammerschmid et al. 2018; Lupiañez-Villanueva et al. 2018).

Please note the following non-reactive instruments for which **Financing & Reimbursement** is of great importance:

- ***Human Assistance Costs*** (see page 110 in Health, page 163 in Care and page 217 in Being Active)
- ***Financial Burden for Users*** (see page 112 in Health, page 165 in Care and page 219 in Being Active)
- ***Operating Materials and Maintenance Costs*** (see page 119 in Health, page 172 in Care and page 226 in Being Active)
- ***Investment, Installation and De-installation Costs*** (see page 122 in Health, page 175 in Care and page 229 in Being Active)

Data Protection & Ethical Issues in Slovenia

Key principles regarding data are (1) transparency, (2) lawful basis for processing, (3) purpose limitation, (4) data minimization, (5) proportionality, (6) retention, (7) data security and, (8) prohibition of discrimination. In addition, key rights that individuals have concerning the processing of personal data are right to (1) access to data/copies, (2) rectification of errors, (3) deletion/right to be forgotten, (4) object to processing, (5) restrict processing, (6) data portability, (7) withdraw consent, (8) right to object to marketing, (9) right to complain to the relevant data protection authorities (Pirc Musar & Lemut Strle 2021).

Please note the following non-reactive instruments for which **Data Protection & Ethical Issues** are of great importance:

- ***Consideration of Ethical Guidelines*** (see page 94 in Health, page 147 in Care and page 201 in Being Active)
- ***State of Health*** (see page 98 in Health, page 151 in Care and page 205 in Being Active)
- ***Active/Passive Usage*** (see page 103 in Health, page 156 in Care and page 210 in Being Active)
- ***Error Data*** (see page 106 in Health, page 159 in Care and page 213 in Being Active)

Health Technology Assessment:

Health technology assessment (HTA) is performed at a very basic level. An important step forward has been the launch of a program for standardizing equipment and introducing technical guidelines. Furthermore, in 2010 the Ministry of Health started with activities to set up an HTA network for the organized and systematic assessment of health care technologies (old and new) for all submitted health technologies proposals (European Commission 2019a).

1.13. Spain

The Spanish National Health System (NHS) follows a model similar to the Beveridge model. The government provides health care coverage for the Spanish population predominantly financed by taxes (Lupiañez-Villanueva et al. 2018; Ministerio de Sanidad 2019; European Commission 2019a).

Health & Care Provision in Spain

The Spanish system combines central, regional and local management structures. At the central level, the Ministry of Health is responsible for the general coordination and basic health legislation, defining basic benefits packages guaranteed by the NHS and pharmaceutical policy and medical education. On the other hand, health and care competencies are in charge of the autonomous communities supervised, governed, and monitored nationally (Bernal-Delgado et al. 2018).

Primary health and care is an integrated system composed of primary health and care centers and multidisciplinary teams providing personal and public health services in well-equipped centers, where general practitioners (GPs) and primary health care pediatricians work. Acting as gatekeepers, they decide about referrals to specialists and hospitals (European Commission 2019a). Secondary health services are specialized outpatient care, inpatient care, day-case care or emergency care, depending on the patient's condition and particular needs offered at hospitals (Bernal-Delgado et al. 2018; European Commission 2018).

Care services are split up between in-kind or cash benefits. Provision works via a network of social centers and services available in the autonomous communities, including regional public institutions, services provided by the municipalities, national reference centers for support of specific causes of disability, and accredited partner private centers. LTC care is provided through the basic social services of regions and municipalities and by programs towards people with disability benefits (European Commission 2019a; Bernal-Delgado et al. 2018).

The development and implementation of eHealth projects have involved continuous coordination between the Ministry of Health and the autonomous communities (Bernal-Delgado et al. 2018).

Please note the following non-reactive instruments for which **Health & Care provision** is of great importance:

- ***Costs and Revenues during Development and Market Launch*** (see 115 in Health, page 168 in Care and page 222 in Being Active)
- ***Market Potential*** (see page 124 in Health, page 177 in Care and page 231 in Being Active)
- ***Avoided Resource Requirements*** (see page 128 in Health, page 181 in Care and page **Fehler! Textmarke nicht definiert.** in Being Active)
- ***Economic Potential from Increased Labour Market Participation and Voluntary Activity*** (see page 235 in Being Active)

Financing & Reimbursement in Spain

In 2019, healthcare is predominantly financed through government schemes (66.6 %) and compulsory contributory health care financing schemes (4.0 %), with an additional 21.8 % from out-of-pocket payments (OOP). Most public funding comes from government schemes, while the contribution of voluntary health insurance (VHI) is at 7.6 % (Eurostat 2021b).

Contract programs or management contracts are the usual tools defining quantitative and qualitative objectives, the budget, and the evaluation system. Though the health care system is fully devolved to the regions, eligibility depends on the general regulations of the central government (European Commission 2019a; Hammerschmid et al. 2018; Rend Europe 2018; Ministerio de Sanidad 2019).

Please note the following non-reactive instruments for which **Financing & Reimbursement** is of great importance:

- ***Human Assistance Costs*** (see page 110 in Health, page 163 in Care and page 217 in Being Active)
- ***Financial Burden for Users*** (see page 112 in Health, page 165 in Care and page 219 in Being Active)
- ***Operating Materials and Maintenance Costs*** (see page 119 in Health, page 172 in Care and page 226 in Being Active)
- ***Investment, Installation and De-installation Costs*** (see page 122 in Health, page 175 in Care and page 229 in Being Active)

Data Protection & Ethical Issues in Spain

A device using information and communication technologies (ICT) in the field of health and care products and services is an instrument, software, material, etc. used for diagnostic and/or therapeutic purposes, intended for the diagnosis, prevention, monitoring, treatment, alleviation or compensation for a disease, an injury or handicap, investigation, replacement or modification of the anatomy or a physiological process, and control of conception, and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means (Gordon et al. 2020).

Compliance with these regulations entails, among other things, analyzing personal data, determining the legal positions of the different parties and identifying the personal data which will be processed. The Spanish Data Protection Act does not contain any special provision for the processing of personal data within a device referring to telemedicine or something else. However, there are some general requirements that could apply, for instance, in regard to the purposes of the processing, data protection rights, privacy policy (Gordon et al. 2020).

Please note the following non-reactive instruments for which **Data Protection & Ethical Issues** are of great importance:

- ***Consideration of Ethical Guidelines*** (see page 94 in Health, page 147 in Care and page 201 in Being Active)
- ***State of Health*** (see page 98 in Health, page 151 in Care and page 205 in Being Active)
- ***Active/Passive Usage*** (see page 103 in Health, page 156 in Care and page 210 in Being Active)
- ***Error Data*** (see page 106 in Health, page 159 in Care and page 213 in Being Active)

Health Technology Assessment:

Health Technologies Assessment (HTA) is present both at a national and regional level. The recent creation of the platform of HTA agencies has marked a turning point in the direction of fostering coordination and synergies (European Commission, 2019).

1.14. Switzerland

Switzerland has a Bismarck health system model based on general and compulsory social insurance (Berger 2017; Lupiañez-Villanueva et al. 2018; De Pietro et al. 2015).

Health & Care Provision in Switzerland

Legislation, implementation, and supervision of public health and care services are split between the federal and cantons covered by mandatory health insurance (MHI), with subsidies for people on low incomes. The system is highly fragmented regarding both organization and planning and health and care provision (De Pietro et al. 2015; Angerer & Liberatore 2018).

There is no gatekeeping through general practitioners (GPs) or other primary level providers. Ambulatory care is provided mostly by self-employed physicians offering both primary care and specialized care. Acute care hospitals provide inpatient care and play an increasingly important role in the provision of ambulatory and daycare services (De Pietro et al., 2015; Finkenstädt 2015).

Cantons are responsible for the organization of long-term care and rehabilitation care but may delegate responsibility to municipalities. As long-term care is mainly organized at the cantonal level, there are no national programs to improve quality, but at the cantonal level (De Pietro et al. 2015; Finkenstädt 2015).

The Federal Law on Electronic Health Records promotes the usage and implementation of eHealth. In 2007, a national eHealth strategy was implemented, coordinating respective developments (De Pietro et al. 2015).

- ***Costs and Revenues during Development and Market Launch*** (see 115 in Health, page 168 in Care and page 222 in Being Active)
- ***Market Potential*** (see page 124 in Health, page 177 in Care and page 231 in Being Active)
- ***Avoided Resource Requirements*** (see page 128 in Health, page 181 in Care and page **Fehler! Textmarke nicht definiert.** in Being Active)
- ***Economic Potential from Increased Labour Market Participation and Voluntary Activity*** (see page 235 in Being Active)

Financing & Reimbursement in Switzerland

In 2019, healthcare is predominantly financed through compulsory contributory health care financing schemes (44.3 %) and government schemes (22.5 %), with an additional 25.3 %

from out-of-pocket payments (OOP). Most public funding comes from the social health insurance schemes, while the contribution of voluntary health insurance (VHI) is 7.9 % (Eurostat 2021b).

Coverage is ensured through mandatory health insurance (MHI), with subsidies for people on low incomes. The federal level and cantons are responsible for funding the health system. Resources are collected mostly through taxes, MHI, out-of-pocket payments, and government spending (Lupiañez-Villanueva et al. 2018; de Pietro & Francetic 2018; de Pietro et al. 2015).

Please note the following non-reactive instruments for which **Financing & Reimbursement** is of great importance:

- ***Human Assistance Costs*** (see page 110 in Health, page 163 in Care and page 217 in Being Active)
- ***Financial Burden for Users*** (see page 112 in Health, page 165 in Care and page 219 in Being Active)
- ***Operating Materials and Maintenance Costs*** (see page 119 in Health, page 172 in Care and page 226 in Being Active)
- ***Investment, Installation and De-installation Costs*** (see page 122 in Health, page 175 in Care and page 229 in Being Active)

Data Protection & Ethical Issues in Switzerland

Providers of digital health solutions must comply with data protection regulations, particularly the Federal Data Protection Act and the General Data Protection Regulation (GDPR) on the European level. Other decrees may be relevant in Switzerland, such as the Federal Law on Human Genetic Testing, the Human Research Act or Acts regulating Electronic Patient Records (EPR; Bühler et al. 2021).

There are principles that must be taken into account when developing and applying services and products in the field of information and communication technologies (ICT): (1) The collection of personal data, and in particular, the purpose of their processing, must be identifiable to the data subject (transparency). (2) Personal data may only be processed for the purpose that was stated at the time of acquisition, is apparent from the circumstances or is provided for by law (purpose limitation). (3) The processing of personal data must be proportionate, i.e. must not go further than the purpose of the processing requires (proportionality). (4) The processor must ensure the accuracy of the personal data and destroy incomplete or inaccurate personal data (data integrity). Personal data must be protected against unauthorized processing by appropriate technical and organizational measures (data security). In Switzerland, truly anonymized data does not fall under data protection laws; therefore, it can be freely used for any purpose, including medical research. However, health data is highly personalized, which makes it complicated (Bühler et al. 2021).

Data security, privacy, liability, personal rights of users, quality assurance, are the cause or ethical issues discussed and mentioned in Switzerland (Bühler et al. 2021).

Please note the following non-reactive instruments for which **Data Protection & Ethical Issues** are of great importance:

- ***Consideration of Ethical Guidelines*** (see page 94 in Health, page 147 in Care and page 201 in Being Active)
- ***State of Health*** (see page 98 in Health, page 151 in Care and page 205 in Being Active)
- ***Active/Passive Usage*** (see page 103 in Health, page 156 in Care and page 210 in Being Active)
- ***Error Data*** (see page 106 in Health, page 159 in Care and page 213 in Being Active)

Health Technology Assessment:

So far, there is limited use of independent health technology assessments (HTA) to inform coverage decisions and to limit expenditures on existing and new services of uncertain benefit. Then the use of medical guidelines could be strengthened to help professionals “choose wisely” when examining and treating patients (De Pietro et al. 2015).

2. Health

In the following, the measuring instruments developed to evaluate the effects of AAL solutions in the area of health are presented.

This implies technologies that aim to maintain or improve health. The target population comprises the users of these solutions. The reactive and non-reactive measuring instruments are based on the gathering of indicators which are summarised below. In addition, it is pointed out whether the respective indicator is to be collected reactively or non-reactively as well as the definition of the indicator and the source(s) that were incorporated into the creation of the operational definition. By clicking on "reactive" or "non-reactive" you can switch directly to the operationalization.

Vitality and Quality of Life Goals

Maintaining, expanding, or improving skills and independent activities:

Subjectively relevant activity level (reactive): Self-performance of activities that contribute to the well-being and are experienced as meaningful. This applies in particular to activities that contribute to maintaining or improving health and life satisfaction (based on Orem 2001; Pratt & Ashforth 2003; Diener, Emmons, Larsen & Griffin 1985).

Cognitive and mental abilities (reactive): The person's self-perceived abilities that relate to perception, thinking, or cognition and serve to fulfill subjectively relevant activities (based on Kent 2006s; Kaminski & Neisser 1994; Zimbardo 1995; Tuomi et al. 1998).

Physical abilities (reactive): Self-perceived physical abilities to perform subjectively relevant activities (based on Kent 2006b; Martin 2015).

Maintaining or improving well-being:

Autonomy & self-determination (reactive): Autonomy is the self-determined making of decisions. The following is subsumed under perceived self-determination: knowing the subjective degree of freedom from (1) obstacles, (2) possibilities of action, (3) choosing possibilities of activity, (4) acting (carrying out activities), and (5) the freedom to create new possibilities of activity for oneself. Self-assessment of opportunities for action concerns (1) overall assessment, (2) subjectively relevant activities, and (3) activities that promote health (based on Thomasma 1984; Mittelstadt, Fairweather, McBride & Shaw 2011).

Life satisfaction (reactive): Life satisfaction refers to an internal norm that is formed in comparison with the social environment and one's own ideals/goals. This concerns both the specific health situation and one's own life as a whole (based on Diener, Emmons, Larsen & Griffin 1985; Frieswijk, Buunk, Steverink & Slaet 2004). An important part of life satisfaction is self-esteem, Self-esteem is an evaluative attitude towards the self in relation to one's own life as a whole and based on assumptions about oneself, which are also based on health-specific factors in the health context (based on Demo & Savin-Williams 1992; Schütz & Sellin 2006).

Perception of safety (reactive): The subjective assessment of self-control, control over others and the environment so that the risks of adverse events are appropriately handled to avoid occurrence. This relates in particular to the perceived likelihood that negative harm to life and health occurs as a result of a hazard (based on Schwartz et al. 2012; Gustafsod 2006; Gorse, Johnston & Pritchard 2012).

Age(ing)-related self-image (reactive): The age(ing)-related self-image is an evaluative assessment based on proactive analysis of oneself and interaction partners about oneself and one's own age (own development).

Maintaining or improving health:

Subjective state of health (reactive): Health is defined as an ideal-typical positive functional overall condition with bio-psycho-social aspects, which is realized along a continuum to the construct "illness". The subjective state of health is defined as a momentary perception and evaluation of one's own health. It is functional in general as well as with regard to meaningful activities (based on Hilfebrandt & Kickbusch 2000; Reichard, Alricsson & Werner 2008; Silva et al. 2018; Lawton & Brody 1969).

Health-promoting behavior (reactive): Health-promoting behavior refers to behavior that is related to maintaining, restoring, and improving health. The adoption of these measures refers to the attitude and actions with which the individual approaches these measures, and is particularly evident in goal-oriented actions or refraining from actions (e.g. health information seeking) (based on Zielegmann 2002; Graffigna et al. 2017; Lawton & Brody 1969).

Social Goals

Promotion of inclusion and participation:

Social interaction (reactive): Social interaction denotes interrelated actions of two or more individuals, e.g. in the form of linguistic communication. Particularly, the focus is on satisfaction with the frequency of interaction, the number of social contacts, and the quality of the interaction (based on Brockhaus Enzyklopädie 1989:560).

Social participation (reactive): Social participation is defined as the degree of subjective participation in society in the sense of a sense of belongingness, participation in subjectively relevant social activities, and the necessary resources and opportunities (based on UNECE 2010:2).

Consideration of ethical criteria during development and implementation:

Consideration of ethical guidelines (non-reactive): The consideration and evaluation of moral actions during the development and use of products and services include, among other things, informed consent, a benefit-risk assessment, and risk minimization measures (based on Gabler 2019).

Freedom of choice regarding service access (reactive): Freedom of choice regarding service access includes the degree of perceived self-determination during the usage of AAL products and services (own development).

Freedom of stigma (reactive): The term “stigma-free” refers to the perceived degree of absence of negative categorization and discrimination based on specific characteristics or attributes that arise from the usage of an AAL solution. This particularly concerns negative attribution due to age(ing) and associated negative stereotypes (based on Goffman 1963; Link & Phelan 2001).

Social System Goals

Improvement of the health system:

Access to and offer of healthcare (reactive): Access to and offer of health services is defined by physical accessibility and acceptance of these. Physical accessibility refers to the availability of care services within a reasonable distance and with suitable opening hours. (based on WHO 2016).

Affordability of healthcare (reactive): Financial affordability means the care or support service can be paid for without much difficulty, which depends, among other factors, on the health financing system and household income. Acceptance concerns people’s willingness to make use and pay for the offers (based on WHO 2016).

Services used (health care system) (reactive): This refers to the use of services of the health care system (inpatient and outpatient sector), medication consumption, and preventive health care (own development).

Therapy adherence/compliance (reactive): Adherence refers to the extent to which a person’s behavior, including medication intake, a diet regime, or lifestyle changes, conforms to the recommendations arranged with the therapist (based on WHO 2003).

Economic and Innovation Goals

Establishment and exploitation of the market potential:

Costs and revenues during development and market launch (non-reactive): Costs are defined as the use or consumption of production factors valued in the form of money (e.g. quantity of input factors or time), which arises within a certain period of time (e.g. months or years). The term “revenues” denotes the generation and utilization of goods and services within a specific accounting period that is performance-related and valued in the form of money (based on Hoitsch & Lingnau 2002:16; von Känel 2008:22).

Market potential (non-reactive): Market potential is defined as the capacity of a market and the total possible sales volumes of a market for a specific product or service. The market potential forms the upper limit for the market volume (based on Gabler 2018).

Willingness to pay (reactive): This refers to the maximum price at which a consumer is willing to buy a unit of a good (based on Jedidi & Jagpal 2009:40).

Business feasibility:

Investment, installation, and de-installation costs (non-reactive): Investment and installation costs include costs for the usage of longer-term assets such as machines, buildings, but also for initial equipment, spare parts, computer systems, etc. De-installation costs arise after the end of the use of the longer-term assets when they are no longer needed (based on Gabler 2018).

Operating materials and maintenance costs (non-reactive): Operating and maintenance costs refer to the consumption of raw materials, auxiliary and operating materials, externally sourced primary products as well as personnel costs for the operation and maintenance of AAL products and components that are valued in the form of money. A distinction is made between performance-variable direct and overhead costs and performance-fixed costs (based on von Känel 2008:150).

Human assistance costs (non-reactive): Human assistance costs refer to the consumption of raw materials, auxiliary and operating materials, externally sourced primary products, and personnel costs for human assistance in the usage of AAL products and components that are valued in the form of money. This includes, among other things, user training as well as support and service information. A distinction is made between performance-variable direct and overhead costs and performance-fixed costs (based on von Känel 2008:150).

Financial burden for users (non-reactive): Periodised expenditure valued in the form of money of a primary, secondary or tertiary user in a periodized accounting period for the usage of AAL products and components (based on Gabler 2018).

Overall economic, financial sustainability:

Avoided resource requirements (non-reactive): Avoided resource requirements are defined as the reduction of costs valued in the form of money in the health care sector within an accounting period in comparison to a reference condition (e.g. without and with the use of AAL products) (own development).

Design and Technology Goals

Acceptance and user experience:

Subjective intention of use (reactive): Subjective intention of use is the behavioral intention of a person to actually use a specific AAL solution for a purpose envisaged in its development (based on Davis 1989; Venkatesh & Bala 2008).

Pragmatic user experience (reactive): User experience is defined as the evaluative perception of an AAL solution by a person resulting from the use and/or the expected use of a system. It concerns functional aspects, especially perceived usability and usefulness (based on ISO 9241-210:2010; Hartsin & Pyla 2012; Raisamo et al. 2012).

Hedonic user experience (reactive): User experience is defined as the evaluative perception of an AAL solution by a person resulting from the use and/or the expected use of a system. The hedonic level especially concerns the emotional impact (based on ISO 9241-210:2010; Hartsin & Pyla 2012; Raisamo et al. 2012).

Stigma-free design (reactive): Freedom of stigma refers to the perceived degree of absence of negative categorization and discrediting based on specific characteristics or attributes that arise from the usage of an AAL solution. This particularly concerns negative attribution due to age(ing) and related negative stereotypes (based on Goffman 1963; Link & Phelan 2001).

Active/Passive usage (non-reactive): Active usage is defined as usage during which users consciously interact with a system (voluntary and controlled input or output). Passive usage is defined as usage during which users do not consciously interact with the system even though it is active (own development).

Safe handling and protection of data:

Privacy from the user perspective (reactive): Privacy from the user's perspective concerns the individual perception of the extent of control over data that the user considers to be personal data. This relates to risk assessments of unauthorized access, unauthorized re-use, concerns that protection against intentional and accidental errors is inadequate, and the extent of data collection (based on Smith, Milberg & Burke 1996; Clarke 1999; Ackerman & Mainwaring 2005; Bélanger & Crossler 2014).

Quality of the technical solution:

Error data (non-reactive): An error is an unexpected system status that results in the inability to perform an intended function. An error can be software-related or hardware-related (based on Butterfield & Ngondi 2016a; Butterfield & Ngondi 2016b).

2.1. Health Questionnaire Instrument for Users of AAL Solutions (Reactive Data Collection)

Notes on the use of questionnaires and the avoidance of process errors

The questionnaire was constructed for usage with older users whose health shall be maintained or improved with the help of the AAL solution. It takes about 20 minutes to answer the full questionnaire which can be classified as adequate for the target group. The questionnaire was constructed for written surveys (paper or digital) for independent interviewing. If the questionnaires are used in contexts where researchers or examiners are present, they should keep their distance in order to signal to the respondents that they do not look at their answers. If questions arise, for example, due to comprehension problems, the examiners should react with as much reserve as possible, suggest to the test persons that there are no wrong answers and, in case of doubt, only paraphrase the formulations. However, they should certainly not suggest answers so as not to influence the results. The layout of the questionnaires should be kept constant at all survey times and illustrations should be avoided. In the case of oral questioning, the answer items should be read aloud, whereby in the case of scales all answer points should be verbalized at least once, and at least the endpoints and the number of points should be mentioned. The possibility of answers is thereby put in front of the first question with the explanation that the respondent should rate the following statement (for the first question: “On a scale of one to five, where one means ‘do not agree at all’, two means ‘rather disagree’, three means ‘neither’, four means ‘rather agree’ and five means ‘completely agree’, how would you rate the following statements:”; and then: “On a scale of one to five, where one means ‘strongly disagree’ and five means ‘strongly agree’, how would you rate the following statements:”). We recommend giving preference to written survey modes. However, in any case, make sure that the mode is not varied over different survey times.

The questionnaire captures the subjective assessment of older users of the status quo or, in the case of retrospective questions, of the last four weeks prior to the time of the survey. It is, therefore, suitable for a variety of research designs and allows, for example, to measure effects over time or to make comparisons with a control group. The measurements of the fulfillment of design and technology goals as well as the items on willingness to pay and freedom of choice regarding service access, which are not presented in the case of (as yet) non-existent technology usage (e.g. control group, measurement of the baseline in the case of pre-post designs), form an exception here.

Instructions for the participants on answering the questions

General instruction

Thank you very much for participating in this survey.

We would like to ask you to complete the following questionnaire. The questions relate to your personal assessments of your health, your well-being, of health care as well as your approach to digital technologies in general and to *<technology>* in particular.

It takes about 20 minutes to complete the questionnaire. Please make sure to answer all questions. Please read each question carefully before answering. There are no right or wrong answers. If you have any questions about this questionnaire, please contact the examiner in charge.

Interim instructions

The scale "Subjectively relevant activity level" is introduced with the following instruction: The following questions refer to your general and health-related well-being. Now please think of activities in your life that you personally feel are particularly important, that do you good or that you experience as meaningful. Write down three such activities in the corresponding "activity" fields and then rate the statements for each activity.

Items "Access & offer healthcare", "Affordability of healthcare", "Services used (health care system)", and "Therapy adherence/-compliance are introduced with the following instruction: The following is about health services in a broad sense, including services financed by public, private or supplementary insurances.

Items

Table 25: Items of the instrument for the evaluation of AAL technologies in the area of health

No.	Item	Subscale
SRA1, SRA4, SRA7	I am satisfied with the degree to which I can carry out the activity myself.	Subjectively relevant activity level
SRA2, SRA5, SRA8	I am satisfied with my mental abilities to carry out the activity.	Subjectively relevant activity level
SRA3, SRA6, SRA9	I am satisfied with my physical abilities to carry out the activity.	Subjectively relevant activity level
AS1	I can make self-determined decisions in my life.	Autonomy & self-determination
AS2	I can decide for myself which activities that are important to me personally I undertake.	Autonomy & self-determination
AS3	I can decide for myself which activities that are important for my health I undertake.	Autonomy & self-determination
SSH1	Concerning my physical abilities, I feel rather...	Subjective state of health
SSH2	Concerning my mental abilities, I feel rather…	Subjective state of health
SSH3	Concerning my social well-being, I feel rather...	Subjective state of health
LS1	I am generally satisfied with my life.	Life satisfaction
LS2	When I think of my ideals and goals, I am satisfied with my life.	Life satisfaction

No.	Item	Subscale
LS3	Compared to other people around me, I am satisfied with my life.	Life satisfaction
LS4	When I think of my ideals and goals, I am satisfied with my health situation.	Life satisfaction
LS5	Compared to other people around me, I am satisfied with my health situation.	Life satisfaction
ARSI1	Compared to my age in years, others perceive me as young.	Age(ing)-related self-image
ARSI2	Compared to my age in years, I perceive myself as young.	Age(ing)-related self-image
ARSI3	I like being as old as I am.	Age(ing)-related self-image
LS6	In general, I am satisfied with myself.	Life satisfaction
LS7	I would not want to change anything about myself.	Life satisfaction
LS8	I am proud of myself.	Life satisfaction
LS9	I am proud of my health.	Life satisfaction
PS1	I feel safe.	Perception of safety
PS3	I think I can keep risks to my health well under control.	Perception of safety
PS4	I think I can control well whether my life is at risk.	Perception of safety
HPB1	I consciously take actions that promote my health (e.g. sports or healthy eating).	Health-promoting behavior
HPB2	I consciously refrain from actions that are harmful to my health (e.g. smoking).	Health-promoting behavior
HPB3	I inform myself about what behavior is considered healthy or harmful to health.	Health-promoting behavior
SI1	I am satisfied with the frequency with which I am in contact with other people.	Social interaction
SI2	I feel part of society.	Social interaction
SI3	I am satisfied with the number of people I am in contact with.	Social interaction
SP1	I have the opportunity to participate in social activities that are important to me.	Social participation
SP2	I am satisfied with the quality of interaction with my personal contacts.	Social participation
SP3	I feel like I belong to a group (e.g. neighborhood, family, sports club).	Social participation
AOH1	I am satisfied with the availability (e.g. opening hours, distance) of health services.	Access & offer healthcare
AH2	I am willing to make my financial contribution for services.	Affordability of healthcare
AH3	Necessary health services are easily financeable for me.	Affordability of healthcare
AOH5	I make use of health services.	Access & offer healthcare
SU1	I have used services (e.g. doctor's visit, prescriptions, inpatient or outpatient stay) in the last four weeks.	Services used (health care system)
SU2	Which health care services?	Services used (health care system)

No.	Item	Subscale
TAC1	I adhere to the agreement concerning my health-related behavior I have made with my doctor (e.g. intake of medication, diet, lifestyle).	Therapy adherence/-compliance
TAC2	My doctor thinks that I am adhering to the agreed health-related behavior.	Therapy adherence/-compliance
WTP1	Now think about <technology>, at what purchase price would this product be too expensive for you?	Willingness to pay
SIU1	How often will you use <technology> next year?	Subjective intention of use
PUX1	The usage of <technology> is simple.	Pragmatic user experience
SFD7	<Technology> emphasize my weaknesses.	Stigma-free design
SFD1	When I use <technology>, I feel old.	Stigma-free design
HUX1	I enjoy using <technology>.	Hedonic user experience
SFD3	People around me perceive me as old when they learn that I use <technology>.	Hedonic user experience
HUX1	I like using <technology>.	Stigma-free design
PUX2	The usage of <technology> supports me in my daily life.	Pragmatic user experience
SFD5	I think that people see me in a different, worse light when they learn that I use <technology>.	Stigma-free design
SFD6	I do not want others to know that I use <technology>.	Stigma-free design
PUX3	The <technology> are useful to me.	Pragmatic user experience
SFD4	I am ashamed to use <technology>.	Stigma-free design
FC1	I can decide for myself whether I use <technology>.	Freedom of choice regarding service access
FC2	I can decide for myself how often I use <technology>.	Freedom of choice regarding service access
PR1	It is likely that someone accesses my <technology> data without permission.	Privacy
PR2	It is likely that someone uses my <technology> data without permission for purposes with which I disagree.	Privacy
PR3	It is likely that my <technology> data is not sufficiently protected due to an error.	Privacy

Additionally, we recommend inquiring about at least the following socio-demographic characteristics at the end of the questionnaire:

Age (in years)
Gender (open)
Highest level of education completed we recommend using national qualification frameworks and transform results to the European Qualification Framework (EQF)).
What was/is your last/current profession?
Planned or past retirement (in (the year))
How often do you use a smartphone, computer, or tablet in everyday life? (very rarely/never, rarely (about 1x per month), occasionally (about 1x per week), often (several times per week), very often (one to several times per day))

Answer specifications

Five-point response format with the options 1 = strongly disagree, 2 = rather disagree, 3 = neither, 4 = rather agree, 5 = strongly agree

Exceptions:

- Items SSH1, SSH2, SSH3: Five-point response format with the options 1 = sick to 5 = healthy
- Item WTP1: From a purchase price of ___ euros
- Item SIU1: Six-point response format with the options 1 = never, 2 = less often than once a month, 3 = monthly, 4 = weekly, 5 = daily, 6 = several times a day
- Item SU3: open (text)

Evaluation notes

In the questionnaire instrument, the respective indicators are operationalized by single or multiple items. For the individual items, we recommend calculating mean values or comparing the absolute numbers. In principle, high values stand for strong agreement and low values for weak agreement.

For indicators that are measured by several items (scales), scale averages are to be formed. Thereby the response values of the assigned items are added up and divided by the number of items. For example, for the scale *autonomy and self-determination*, the values of the items AS1, AS2, and AS3 are added together and then divided by three. The following list shows all items per multi-item subscale:

- Access & offer healthcare: AOH1, AOH5
- Affordability of healthcare: AH2; AH3
- Age(ing)-related self-image: ARSI1, ARSI2, ARSI3
- Autonomy & self-determination: AS1, AS2, AS3
- Freedom of choice regarding service access: FC1, FC2
- Health-promoting behavior: HPB1, HPB2, HPB3
- Hedonic user experience: HUX2, HUX3
- Life satisfaction: LS1, LS2, LS3, LS4, LS5, LS6, LS7, LS8, LS9

- Perception of safety: PS1, PS3, PS4
- Pragmatic user experience: PUX1, PUX4, PUX5,
- Privacy: PR1, PR2, PR3
- Social interaction: SI1, SI2, SI3
- Social participation: SP1, SP2, SP3
- Stigma-free design: SFD1, SFD3, SFD4, SFD5, SFD6, SFD7
- Subjective state of health: SSH1, SSH2, SSH3
- Subjectively relevant activity level: SRA1, SRA2, SRA3, SRA4, SRA5, SRA6, SRA7, SRA8, SRA9
  Therapy adherence/-compliance: TAC1, TAC2

In general, missing values should be avoided in the survey. In the case of an online survey, it is recommended to make answering the items compulsory. Furthermore, we recommend that an evaluation is only carried out when at least three questionnaires have been completed in order to avoid violation of anonymity. It must be noted that the principal component analyses showed several cross-loadings. However, these cross-loadings are in line with the definitions of the indicators, but we recommend calculating intercorrelations of the respective scales.

2.2. Collection of Key Figures (Non-reactive Data Collection)

Consideration of Ethical Guidelines

Definition:
The consideration and evaluation of moral actions during the development and usage of products and services include, among other things, informed consent, a benefit-risk assessment, and measures to minimize risk.

Source of data:
R&D performing institution/company/product developers

The developers or project teams can provide insight into the extent to which ethical guidelines are taken into account in developing and using AAL products and services. The following definition is used for the term ethics (Gabler 2019): “Ethics is the doctrine or theory of action according to the distinction between good and evil. The subject matter of ethics is morality. Greek ethics was empirical and normative at the same time. Today, empirical, descriptive ethics is strictly distinguished from normative ethics, which formulates an ought; this ought makes a claim to be generally binding.”

Object of measurement:
The compliance with ethical guidelines in the development and use of products and services in the field of AAL is measured, taking into account the special needs of older people. At this point, it should be mentioned that this is not exclusively a technology goal, but that exit strategies and similar ethical considerations must also be included.

The following questions can be helpful for the assessment of compliance with ethical guidelines (Felnhofer et al. 2013):

- **Recruitment of participants:**
  - Was the aim of the study explained during recruitment?
- **Benefit-risk assessment:**
  - Have potential risks been identified?
  - Have all steps been taken to minimize the risks?
  - Do the benefits justify the risks?
- **Informed consent:**
  - Was informed consent (IC) given?
  - Did the IC include the following points:
    - aim of the survey
    - duration and procedure of the survey
    - indication of the voluntary nature of participation

        - indication of the possibility to opt-out of the survey at any time and, if so, how to do this
        - explanation of benefits
        - indication of risks
        - contact for further queries
    - Is the information formulated in a comprehensible way and formatted in an age-appropriate way?
    - Has a consent form been signed?
- **Exit strategies**
    - Are there considerations on how to end the project?
    - Is the sustainability of the project ensured beyond its duration?
- **Ethics committee**
    - Has an ethics committee approved the project?

Time of measurement:
Ethical questions must already be clarified or taken into account during the planning or development of AAL products and services. At the latest, however, before the practical application on humans, it should be possible to answer the issues mentioned positively before the test phase.

Measurement mode:
An interrogative process with the help of guidelines as well as codes can accompany the consideration of ethical guidelines. In this context, checklists (see e.g. Felnhofer et al. 2013) can have a supportive effect.

Further notes:
Is there a manual that describes the entire development process and includes ethical considerations?

Another useful tool to include ethical considerations in the development process can be the Gender Sensitive Research Cycle (European Commission DG Research & Innovation 2011:14). The approach is twofold, on the one hand involving men and women equally and thus creating equal opportunities. On the other hand, this approach includes “gender” from the beginning to the end, from the project idea to the publication of the results.

Databases and cross-references to country-specific information:

European Union

- Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (Text with EEA relevance, here Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (Text with EEA relevance)
- Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC Text with EEA relevance (European Parliament and Council of the European Union, 24 May 2014, here: Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC Text with EEA relevance)
- Ethics and data protection (European Commission, 5 July 2021, here: Ethics and data protection)
- Guidelines 05/2020 on consent under Regulation 2016/679 (European Data Protection Board, 4 May 2020, here: Guidelines 05/2020 on consent under Regulation 2016/679)
- Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (Text with EEA relevance, here Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (Text with EEA relevance.))
- Assessment of the EU Member States' Rules on Health Data in the Light of GDPR (European Commission 2021, here Assessment of the EU Member States' Rules on Health Data in the Light of GDPR)
- Handbook on European Data Protection Law (Publications Office of the European Union 2018, here Handbook on European data protection law

Austria (for country-specific information see page 43)

- Digital Health Laws and Regulations 2021 (Global Legal Group 2021, here: Austria: Digital Health Laws and Regulations 2021)

Belgium (for country-specific information see page 47)

- Digital Health Laws and Regulations 2021 (Global Legal Group 2021, here: Belgium: Digital Health Laws and Regulations 2021)

Cyprus (for country-specific information see page 49)

Hungary (for country-specific information see page 51)

Italy (for country-specific information see page 54)

- Digital Health Laws and Regulations 2021 (Global Legal Group 2021, here: Italy: Digital Health Laws and Regulations 2021)

Luxembourg (for country-specific information see page 57)

Netherlands (for country-specific information see page 61)

Norway (for country-specific information see page 64)

- Data Protection Laws and Regulations 2021 (Global Legal Group 2021, here: Norway: Data Protections Laws and Regulations 2021)
- Guidelines by The Norwegian National Research Ethics Committee for Medical and Health Research (NEM) (Norwegian National Research Ethics Committee for medical and health research 2019, here: Guidelines by The Norwegian National Research Ethics Committee for medical and health research (NEM))

Poland (for country-specific information see page 67)

Portugal (for country-specific information see page 70)

Romania (for country-specific information see page 72)

Slovenia (for country-specific information see page 76)

- Data Protection Laws and Regulations 2021 (Global Legal Group 2021, here: Slovenia: Data Protections Laws and Regulations 2021)

Spain (for country-specific information see page 79)

- Digital Health Laws and Regulations 2021 (Global Legal Group 2021, here: Spain: Digital Health Laws and Regulations 2021)

Switzerland (for country-specific information see page 81)

- Digital Health Laws and Regulations 2021 (Global Legal Group 2021, here: Switzerland: Digital Health Laws and Regulations 2021)

State of Health

Definition:
In addition to the subjective state of health (based on Erhart et al. 2006:321ff), characterized by an independent assessment of one's own health, health should also be surveyed. For example, it can be determined via vital parameters (e.g. pulse, blood pressure, body temperature, respiration, etc.); clinical parameters (e.g. pulmonary function capacity, etc.); laboratory parameters (e.g. sodium, potassium, blood count, etc.); the number of risk factors; degrees of disability and restriction or diagnosed diseases.

Source of data:
Users and/or electronic health records (EHRs)

Concerning AAL solutions, the project team can partly collect objective health data directly from the users. The various devices provide vital and laboratory parameters. The users can also give insight into anonymized medical history via electronic health records (EHRs).

Object of measurement:
For measuring the objective state of health, for example, vital parameters, laboratory parameters, diagnosed diseases, and risk factors from the user's medical history and automated recording can be used. At least two measurements are necessary to establish comparisons. The following table gives an overview of potential measurement parameters and the distinction between the subjective and objective state of health.

Table 26: Subjective and objective state of health

Subjective state of health	e.g., own assessment of my health today
Objective state of health	Vital parameters (e.g., pulse, blood pressure, body temperature, respiration, etc.)
Objective state of health	Clinical parameters (e.g., oxygen saturation, pulmonary function capacity, etc.)
Objective state of health	Laboratory parameters (e.g., sodium or potassium concentration, blood count, etc.)
Objective state of health	Number and type of risk factors (e.g., smoking, alcohol, exercise) Degree of disability and restriction (e.g. level of care allowance)
Objective state of health	Diagnosed (pre-existing) diseases

Source: own representation

For the application area of health, vital parameters that measure, for example, health-promoting behavior (e.g., blood pressure or pulse) can be used as objects of measurement.

Time of measurement:
In order to be able to compare the measurement results, several measurement dates are appropriate. Measurement should be arranged before the introduction of the AAL solution in order to be able to present potential changes after the introduction of the technology. Ideally, an intervention and control group are formed and continuous measurements are performed over the entire course of the project.

Measurement mode:
Measurement is made by manual reading of the devices or the documentation or by automatic evaluations of the laboratory devices. Medical professionals should be consulted for the interpretation of data.

Further notes:
Previously, there were discussions with experts and within the research team as to whether the indicators subjective health status and objective health status are comparable and which indicator is best suited for describing the state of health and should therefore be included in the indicator set.

In a large study (n=16,074) in China, Wu et al. (2013) were able to prove that the subjective state of health is consistent with the objective state of health and can be used as a general benchmark for the common population. Even among people over 60 years of age, the subjective state of health is comparable to the objective state of health according to a Chinese study (n=1,096) by Meng et al. (2014).

Nevertheless, the project team suggests collecting relevant data on the state of health subjectively and objectively for the respective AAL solution if possible. In the AAL setting, invasive measurements should be avoided. These are exclusively located in clinical settings.

Databases and cross-references to country-specific information:

European Union

- Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (Text with EEA relevance, here: Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (Text with EEA relevance)
- Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC Text with EEA relevance (European Parliament and Council of the European Union 24 May 2014, here: Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC Text with EEA relevance)
- Ethics and data protection (European Commission 5 July 2021, here: Ethics and data protection)
- Guidelines 05/2020 on consent under Regulation 2016/679 (European Data Protection Board 4 May 2020, here: Guidelines 05/2020 on consent under Regulation 2016/679)
- Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (Text with EEA relevance, here: Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (Text with EEA relevance.))
- Assessment of the EU Member States' Rules on Health Data in the Light of GDPR (European Commission 2021, here: Assessment of the EU Member States' Rules on Health Data in the Light of GDPR)
- Handbook on European Data Protection Law (Publications Office of the European Union: 2018, here: Handbook on European data protection law

Austria (for country-specific information see page 43)

- Electronic health records, i.e., Elektronische Gesundheitsakte (see here: ELGA)
- Digital Health Laws and Regulations 2021 (Global Legal Group 2021, here: Austria: Digital Health Laws and Regulations 2021)

Belgium (for country-specific information see page 47)

- Electronic health records, i.e., Summarized Electronic Health Record (see here: SUMHER)
- Digital Health Laws and Regulations 2021 (Global Legal Group 2021, here: Belgium: Digital Health Laws and Regulations 2021)

Cyprus (for country-specific information see page 49)

Hungary (for country-specific information see page 51)

- Electronic health records, i.e., Elektronikus Egészségügyi Szolgáltatási Tér (see here: EESZT)

Italy (for country-specific information see page 54)

- Electronic health records, i.e., Fascicolo Sanitario Elettronico (see here: Fascicolo Sanitario Elettronico)
- Digital Health Laws and Regulations 2021 (Global Legal Group 2021, here: Italy: Digital Health Laws and Regulations 2021)

Luxembourg (for country-specific information see page 57)

- Electronic health records, i.e., Dossier de soins partagé (see here: DSP)

Netherlands (for country-specific information see page 61)

- Electronic health records, i.e., Persoonlijke gezondheidsomgeving (see here PGO)

Norway (for country-specific information see page 64)

- Electronic health records, i.e., Digital Health Services (see here: HELSENORGE)
- Data Protection Laws and Regulations 2021 (Global Legal Group 2021, here: Norway: Data Protections Laws and Regulations 2021)
- Guidelines by The Norwegian National Research Ethics Committee for Medical and Health Research (NEM) (Norwegian National Research Ethics Committee for medical and health research 2019, here: Guidelines by The Norwegian National Research Ethics Committee for medical and health research (NEM))

Poland (for country-specific information see page 67)

- Electronic health services and records, i.e. E-usługi (see here: E-usługi)

Portugal (for country-specific information see page 70)

- Electronic health records, i.e., ePortugal (see here: ePortugal)

Romania (for country-specific information see page 72)

- Electronic health records, i.e., Dosarul Electronic de Sănătate (see here: DES)

Slovenia (for country-specific information see page 76)

- Electronic health records, i.e., zVEM (see here: zVEM)
- Data Protection Laws and Regulations 2021 (Global Legal Group 2021, here: Slovenia: Data Protections Laws and Regulations 2021)

Spain (for country-specific information see page 79)

- Electronic health records, i.e., É-Saúde (see here: É-Saúde)
- Digital Health Laws and Regulations 2021 (Global Legal Group 2021, here: Spain: Digital Health Laws and Regulations 2021)

Switzerland (for country-specific information see page 81)

- Electronic health records, i.e., Elektronisches Patientendossier (see here: EPD)
- Digital Health Laws and Regulations 2021 (Global Legal Group 2021, here: Switzerland: Digital Health Laws and Regulations 2021)

Active/Passive Usage

Definition:
Active usage is when users consciously interact with a system (voluntary and controlled input or output). Passive usage is defined as when the system is active but the users do not consciously interact with it.

Source of data:
Users or software

The respective developed software serves as the data source. Within the framework of the development of the AAL solution, care must be taken to ensure that this solution's active and passive usage can be recorded by the software.

Object of measurement:
During project planning, the research team must determine what is understood as active usage or passive usage in the concrete case of application. Active usage is, for example, when users actively use the tablet to chat, play games or look at their health data. An example of passive usage is the pedometer, which is integrated into the smartwatch and runs in the background.

Time of measurement:
Data on usage should be collected continuously so that changes over time can be accurately represented. If possible, researchers should collect data over the entire project period.

Measurement mode:
How data can be retrieved depends on the respective project structure and software. Usually, the recorded activity data are stored in databases, which can then be readout.

Further notes:
Data on active/passive usage allows concluding the usage behavior of participants. Davis et al. (1989) have shown with the technology acceptance model that using technology is centrally dependent on two variables: perceived usefulness and perceived ease-of-use. The usage behavior subsequently influences whether and which effects the technical system has on everyday life and the subjective quality of life of the target group (Kada et al. 2017:23).

Databases and cross-references to country-specific information:

European Union

- Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (Text with EEA relevance, here Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (Text with EEA relevance)
- Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC Text with EEA relevance (European Parliament and Council of the European Union 24 May 2014, here: Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC Text with EEA relevance)
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- Guidelines 05/2020 on consent under Regulation 2016/679 (European Data Protection Board 4 May 2020, here: Guidelines 05/2020 on consent under Regulation 2016/679)
- Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (Text with EEA relevance, here: Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (Text with EEA relevance.))
- Assessment of the EU Member States' Rules on Health Data in the Light of GDPR (European Commission 2021, here: Assessment of the EU Member States' Rules on Health Data in the Light of GDPR)
- Handbook on European Data Protection Law (Publications Office of the European Union 2018, here: Handbook on European data protection law

Austria (for country-specific information see page 43)

- Digital Health Laws and Regulations 2021 (Global Legal Group 2021, here: Austria: Digital Health Laws and Regulations 2021)

Belgium (for country-specific information see page 47)

- Digital Health Laws and Regulations 2021 (Global Legal Group 2021, here: Belgium: Digital Health Laws and Regulations 2021)

Cyprus (for country-specific information see page 49)

Hungary (for country-specific information see page 51)

Italy (for country-specific information see page 54)

- Digital Health Laws and Regulations 2021 (Global Legal Group 2021, here: Italy: Digital Health Laws and Regulations 2021)

Luxembourg (for country-specific information see page 57)

Netherlands (for country-specific information see page 61)

Norway (for country-specific information see page 64)

- Data Protection Laws and Regulations 2021 (Global Legal Group 2021, here: Norway: Data Protections Laws and Regulations 2021)
- Guidelines by The Norwegian National Research Ethics Committee for Medical and Health Research (NEM) (Norwegian National Research Ethics Committee for medical and health research 2019, here: Guidelines by The Norwegian National Research Ethics Committee for medical and health research (NEM))

Poland (for country-specific information see page 67)

Portugal (for country-specific information see page 70)

Romania (for country-specific information see page 72)

Slovenia (for country-specific information see page 76)

- Data Protection Laws and Regulations 2021 (Global Legal Group 2021, here: Slovenia: Data Protections Laws and Regulations 2021)

Spain (for country-specific information see page 79)

- Digital Health Laws and Regulations 2021 (Global Legal Group 2021, here: Spain: Digital Health Laws and Regulations 2021)

Switzerland (for country-specific information see page 81)

- Digital Health Laws and Regulations 2021 (Global Legal Group 2021, here: Switzerland: Digital Health Laws and Regulations 2021)

Error Data

Definition:
Error data is divided up into two groups: subjective and objective errors. A subjective error occurs in the case of an unsuccessful attempt to perform a task, regardless of where the cause is subjectively located (software, hardware, user). An objective error or unexpected system status occurs when an intended function cannot be carried out. Such an error can be software-related or hardware-related.

Source of data:
Logfile of the developed software/survey among users in a laboratory setting through usability test/evaluation of helpdesk data

In the first step, the research team has to identify the unexpected behavior (the error) in the log file or database or observe it in a laboratory setting. In the next step, researchers can evaluate the data/observations and subsequently analyze this information.

Object of measurement:
The number and extent of subjective and objective errors are measured. What exactly constitutes an error must be determined individually by the research team for each project. The errors can be divided into subjective errors triggered by the user, e.g. by clicking incorrectly in the software, incorrect configuration of wearables, etc., and objective errors, e.g. no GPS reception on the smartwatch. Furthermore, the project team can categorize the different errors, e.g. severity of the error, system aspects affected, reproducibility, error triggered by software, hardware, or user.

Time of measurement:
Typically, error data are recorded continuously and changes can be accurately represented over a period of time. If possible, researchers should collect, evaluate and analyze the entire measurement period.

Measurement mode:
How data are measured must be adapted individually. The techniques of data validation (checking the entered or recorded data for completeness and usefulness) & pattern recognition (automatic recognition of patterns, regularities, repetitions, or laws) can support this process (ÖNORM 2011:5ff).

In the case of subjective error data, e.g. collected through the number of calls to the helpdesk, these can be analyzed according to the type, extent, and duration of the error. The procedure could look like this, for example: A process is defined. Afterward, an initial check takes place in the laboratory setting to see whether the test persons adhere to the process as planned (similarity to users is important). Parallel to this, an evaluation is carried out by experts, and

any errors are corrected. Finally, the product/service can be rolled out. Also during the field test, there should be a constant evaluation of possible errors and potential corrections of these.

Further notes:
Here, reference can be made to EN ISO 9241-110 (2006:4-8f), in which the seven dialogue principles for interactive systems are defined. One such principle is fault tolerance. In this context, Hofmann (2008) points out that a system that acts interactively must demonstrate fault tolerance to its user. “This means that, on the one hand, it prevents the user from making mistakes - for example, by means of clearly understandable security questions, but on the other hand, it constructively supports the user in the event of an error so that the error can be rectified without too much effort.

Within the framework of the evaluation of the indicator, it is therefore also relevant to constructively discuss the causes of the errors that have occurred as well as improvement potentials. Accordingly, updates of the software or the like to improve the usability of the system are also to be treated as data discontinuity in the measurement period.

A potential parallel reactive questioning of the users about the errors that occurred can broaden understanding of the AAL solution and better explain user behavior. The results about the errors that occurred and their correction should be incorporated in training and documentation.

The ISO 9241-210 2010 standard provides many checklists that can support the process of designing usable interactive systems. These checklists include, for example, items on principles of human-centered design, planning of human-centered design, and human-centered design activities.

Databases and cross-references to country-specific information:

European Union

- Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (Text with EEA relevance, here: Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (Text with EEA relevance)
- Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC Text with EEA relevance (European Parliament and Council of the European Union 24 May 2014, here: Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC Text with EEA relevance)
- Ethics and data protection (European Commission 5 July 2021, here: Ethics and data protection)
- Guidelines 05/2020 on consent under Regulation 2016/679 (European Data Protection Board 4 May 2020, here: Guidelines 05/2020 on consent under Regulation 2016/679)
- Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (Text with EEA relevance, here Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (Text with EEA relevance.))
- Assessment of the EU Member States' Rules on Health Data in the Light of GDPR (European Commission, 2021, here Assessment of the EU Member States' Rules on Health Data in the Light of GDPR)
- Handbook on European Data Protection Law (Publications Office of the European Union, 2018, here Handbook on European data protection law

Austria (for country-specific information see page 43)

- Digital Health Laws and Regulations 2021 (Global Legal Group, 2021, here: Austria: Digital Health Laws and Regulations 2021)

Belgium (for country-specific information see page 47)

- Digital Health Laws and Regulations 2021 (Global Legal Group, 2021, here: Belgium: Digital Health Laws and Regulations 2021)

Cyprus (for country-specific information see page 49)

Hungary (for country-specific information see page 51)

Italy (for country-specific information see page 54)

- Digital Health Laws and Regulations 2021 (Global Legal Group, 2021, here: Italy: Digital Health Laws and Regulations 2021)

Luxembourg (for country-specific information see page 57)

Netherlands (for country-specific information see page 61)

Norway (for country-specific information see page 64)

- Data Protection Laws and Regulations 2021 (Global Legal Group, 2021, here: Norway: Data Protections Laws and Regulations 2021)
- Guidelines by The Norwegian National Research Ethics Committee for Medical and Health Research (NEM) (Norwegian National Research Ethics Committee for medical and health research 2019, here: Guidelines by The Norwegian National Research Ethics Committee for medical and health research (NEM))

Poland (for country-specific information see page 67)

Portugal (for country-specific information see page 70)

Romania (for country-specific information see page 72)

Slovenia (for country-specific information see page 76)

- Data Protection Laws and Regulations 2021 (Global Legal Group 2021, here: Slovenia: Data Protections Laws and Regulations 2021)

Spain (for country-specific information see page 79)

- Digital Health Laws and Regulations 2021 (Global Legal Group 2021, here: Spain: Digital Health Laws and Regulations 2021)

Switzerland (for country-specific information see page 81)

- Digital Health Laws and Regulations 2021 (Global Legal Group 2021, here: Switzerland: Digital Health Laws and Regulations 2021)

Human Assistance Costs

Definition:
Human assistance costs are defined as consumption of raw materials, auxiliary and operating materials, externally sourced primary products (material costs), and personnel costs for human assistance in the usage of AAL products and components. This includes, among other things, user training as well as support and service activities.

Source of data:
Providers of the AAL product or service and secondary data and/or official statistic authorities

The costs or price of an AAL product or service includes all costs and follow-up costs incurred by the user from the usage of an AAL product or service (based on Scharf, Schubert & Hehn 2015:337). This includes user training and support as well as service information. This measuring guide focuses on the immediate costs that arise from the use of an AAL solution. Medium- to long-term costs are discussed in more detail in the measuring guide for operating materials and maintenance costs.

If the provider of the AAL product or service does not provide the relevant information, secondary data from official statistics can be used for approximating the data needed. The data is broken down by industry (Statistical classification of economic activities in the European Community; i.e., NACE) and/or by occupation (International Standard Classification of Occupations; i.e.; ISCO) in the respective countries. In the case of international comparative analyses, it is essential to take the respective national purchasing power standard (PPS) into account in the analysis.

Object of measurement:
Human assistance costs are direct costs that can arise when using the AAL product or the AAL service, e.g. training of users, service information at helpdesks, or support services. The research project IntegrAAL distinguishes three categories of assistance costs depending on the necessary qualification of the respondents (based on Kumpf et al. 2014:93f):

- Level A: Assistance work can be performed by any person
- Level B: Assistance work does not require specific qualification, but good physical general condition
- Level C: Assistance work requires specific professional qualifications, e.g. doctors, certified caregivers, computer technicians

A potentially helpful categorization of assistance costs is to be determined by the project team for the specific AAL application. Costs for human assistance are not only characterized by personnel costs. For example, when a qualified nurse carries out diabetes training, he/she will need blood glucose meters, blood glucose test strips, training material, etc.

Time of measurement:
Costs for human assistance of the application of the AAL products and services should be recorded on the one hand for specific time intervals (e.g. month of commissioning) and on the other hand for the total duration of the project (based on OECD 2018:152).

Measurement mode:
Data should be requested from the AAL product or service providers, as they are most qualified to provide information on the respective costs or can draw on empirical values. Data can be collected in different ways, e.g. with a paper or online questionnaire, by telephone, or through personal interviews (based on OECD 2018:218).

Databases and cross-references to country-specific information:

European Union and EFTA

- Database - Labour Market (incl. LFS). (n.d.). Eurostat (see here: Earnings)
- Database - Purchasing power parities. (n.d.). Eurostat (see here: Purchasing power parities)

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Financial Burden for Users

Definition:
Periodized expenditure valued in the form of money by a primary, secondary or tertiary user in a periodized accounting period for the usage of AAL products and components.

Source of data:
Providers of the AAL solution/developers as well as users and secondary data and/or official statistic authorities

The research team collects data from the AAL product or service providers or from the *primary*, *secondary* or *tertiary* users. Primary users are people who benefit directly from AAL, secondary indirect users such as formal and informal health and care service providers, and tertiary users are those who do not use AAL directly but are involved in its organization and financing in some way or other (e.g. political decision-makers, representatives of social and/or private insurance companies).

In international comparative analyses, it is essential to consider the respective national purchasing power standard (PPS) as well as the corresponding Classification of Individual Consumption by Purpose (COICOP) in the analysis.

Object of measurement:
The total financial burden for primary, secondary or tertiary users includes investment and de-investment costs (see **investment, installation and de-installation costs**; e.g. **acquisition costs of the AAL product, installation costs, training costs, and de-installation costs**) as well as costs for ongoing operation and maintenance (see **operating materials and maintenance costs**; e.g. **electricity costs, insurance, repairs or technical operating costs**). Furthermore, additional service costs can arise that are attributable to the AAL product or service. The following table contains a comprehensive presentation of cost positions that should be recorded.

Table 27: Burden categories

Investment costs (and de-investment costs):
Acquisition costs
Installation costs
Training for (end) users and others
De-installation costs (e.g. after project completion, after death, after a change of care type)
Costs of ongoing operation/maintenance:
Technical operating costs
Repairs
Insurances
Electricity costs
Emergency services etc.
Additional service costs (attributable to AAL product)

Source: Kumpf et al. 2014:92ff; own representation

Time of measurement:
Costs should be reported for the entire period when the user uses the AAL product or service. This approach is supposed to ensure an exact allocation of costs; regardless of the actual outgoing payment (based on OECD 2018:152).

Measurement mode:
Data should be requested from the AAL product or the AAL service providers, as they are most qualified to provide information on the respective costs or can draw on empirical values. However, certain parameters, such as electricity consumption, possibly need to be requested directly from the users. Data can be collected in various ways, e.g. by paper or online questionnaires, telephone, or personal interviews (based on OECD 2018:218).

Further notes:
“Prior to the start of the project, it has to be clarified which form of cost allocation and recording will actually be carried out. AAL projects are usually characterized by specific cost units (funding agencies, non-profit, and other project partners), i.e. in some cases market prices are not charged in projects or market prices are not yet available, which could partly impede a realistic cost calculation.” (based on Kumpf et al. 2014:93ff). If market prices are already available, they should be used to ensure a realistic representation of the financial burden for end users.

Databases and cross-references to country-specific information:

European Union and EFTA

- Database - Labour Market (incl. LFS). (n.d.). Eurostat (see here: Earnings)
- Database - Purchasing power parities. (n.d.). Eurostat (see here: Purchasing power parities)

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Costs and Revenues during Development and Market Launch

Definition:
Costs are defined as the usage or consumption of production factors valued in the form of money (e.g. quantity of input factors or time), which arise within a certain period of time (e.g. months or years).

Revenues denote the performance-related creation of goods and services, valued in the form of money, as well as their utilization within a specific accounting period (based on Hoitsch & Lingnau 2007:16; von Känel 2008:22).

Source of data:
R&D performing institution/company/product developers and secondary data and/or official statistic authorities

On the one hand, the primary focus of companies is on cost minimization, i.e. the prime costs in the development and production of AAL solutions/components should be as low as possible, and, on the other hand, it is on revenue maximization, so that company profits are developed to the maximum.

The measurement of costs and revenues should take place at the institution/company/product developers carrying out R&D since they bear the responsibility for the costs and are obliged to document these due to applicable legal regulations (based on Ehrlenspiel et al. 2005:5).

If the developer of the AAL product or service does not provide the relevant information, secondary data from official statistics can be used for approximating the data needed. The data is broken down by industry (Statistical classification of economic activities in the European Community; i.e., NACE) and/or by occupation (International Standard Classification of Occupations; i.e.; ISCO) in the respective countries. In international comparative analyses, it is essential to consider the respective national purchasing power standard (PPS) as well as the corresponding Classification of Individual Consumption by Purpose (COICOP) in the analysis.

Object of measurement:
The categories listed in the following table are to be used to determine the **costs** involved in the development and market launch of AAL solutions/components.

Table 28: Categories of R&D expenses

Sum of R&D expenses
Capital expenditure
Land and buildings
Machinery and equipment
Activated computer software
Other products of intellectual property
Current expenses
Personnel expenses
Other current expenses
Operating materials and maintenance costs

Source: Based on OECD (2018:142); own representation

R&D capital expenditure is the gross annual amount paid for the acquisition of assets for the performance of research and development that are used repeatedly or continuously for more than one year. R&D capital expenditures include tangible assets (physical assets such as buildings and facilities or machinery and equipment) and intangible assets (e.g. computer software and other intellectual property products).

Current R&D expenses are composed of R&D-related personnel and other current expenses. Services and goods (including equipment) consumed within one year are included in current expenses. Annual fees or rents for the use of assets should also be considered in current expenses (based on OECD 2018:129).

Personnel expenses include remuneration for employed, non-independent R&D staff, such as annual wages and salaries and any related costs or fringe benefits (e.g. bonus payments, stock options, and holiday pay, in addition to pension and other social security contributions, payroll taxes, and duties, etc.). It is important to consider personnel expenses for employees only to the extent to which they contribute directly to research and development (based on OECD 2018:130).

Other current R&D expenses are defined as purchases and rentals of materials, commodity goods, equipment, and services from private or public institutions that do not fall in the category of investments within a reference year (e.g. water, gas, electricity, specialist books, journals, royalties and license fees for the use of patents and other intellectual property rights, or leasing of capital goods; based on OECD 2018:132). Administrative and overhead costs (e.g. office space, IT and telecommunications, building maintenance, insurance) should also be included in other current expenses and prorated if necessary (based on OECD 2018:133).

The sums of R&D expenditures of a project or product development should be recorded and reported at purchase prices. Purchase prices are prices paid by research institutions and companies without taking into account deductible percentages of VAT and similar taxes. These reflect the actual costs incurred during the research and development of AAL solutions (based on OECD 2018:136).

With regard to **revenues**, it can be assumed that R&D performing institutions and facilities such as companies, universities, and universities of applied sciences are financed by third-party funds from national or international research funding, by contract research from public and private economy, or by subsidies and financial aid. In some cases, R&D is financed at least partially or exclusively with internal means (equity capital) (based on OECD 2018:149f).

The (imputed) profit or loss for the project duration is calculated from the difference between the revenues related to the time period and the costs to be compared with them (based on von Känel 2008:197).

Time of measurement:
Costs and revenues should be reported for the period in which R&D is conducted and not for the period in which own or third-party funds have been received (based on OECD 2018:152). This is to ensure an exact allocation of costs and revenues to the respective R&D process, regardless of the actual incoming or outgoing payments.

Measurement mode:
Data can be collected in different ways, e.g. with a paper or online questionnaire, by telephone, or through personal interviews. If accessible, data could also be obtained from administrative sources of the public sector (based on OECD 2018:218). Personal coordination with the institution conducting R&D is recommended in any case to avoid misunderstandings.

Further notes:
It must be clarified before and during the course of the project which of the cost parameters presented above are to be recorded. Development costs are particularly difficult to determine, as they are often based on already existing projects. For this reason, only the research and development costs attributable to the project should be recorded if possible.

Databases and cross-references to country-specific information:

European Union and EFTA

- Database - Labour Market (incl. LFS). (n.d.). Eurostat (see here: Earnings)
- Database - Purchasing power parities. (n.d.). Eurostat (see here: Purchasing power parities)

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Operating Materials and Maintenance Costs

Definition:
The consumption of raw materials, auxiliary and operating materials, externally sourced primary products (material costs) as well as personnel costs for the operation and maintenance of AAL products and components valued in monetary terms (based on von Känel 2008:150).

Source of data:
Providers of the AAL product and/or AAL service and secondary data and/or official statistic authorities

The cost or price of an AAL product or service includes all costs and follow-up costs incurred by primary, secondary, or tertiary users from the usage of an AAL product or service (based on Scharf et al. 2015:337). This measurement guide focuses on running costs that arise from the usage of an AAL solution. These particularly include **running costs** for **operating materials and maintenance costs**. **One-off costs** such as **investment, installation, and de-installation costs** or **human assistance costs** are discussed in more detail in another measurement guide.

If the provider of the AAL product or service does not provide the relevant information, secondary data from official statistics can be used for approximating the data needed. The data is broken down by industry (Statistical classification of economic activities in the European Community; i.e., NACE) and/or by occupation (International Standard Classification of Occupations; i.e.; ISCO) in the respective countries. In international comparative analyses, it is essential to consider the respective national purchasing power standard (PPS) as well as the corresponding Classification of Individual Consumption by Purpose (COICOP) in the analysis.

Object of measurement:
Operating materials and maintenance costs are a sub-category of the category “other current expenses” of the indicator “costs and revenues during development and market launch”.

Running costs of operation and maintenance of AAL products and services (e.g. technical operating costs, repairs, insurance, emergency services for a telemonitoring system) should be recorded and reported at purchase prices. Purchase prices are the prices paid by primary, secondary, and tertiary users without taking into account the deductible percentage of VAT and similar taxes. Purchase prices reflect the actual costs incurred by users (based on OECD 2018:136; Kumpf et al. 2014:93).

Any personnel costs that are research-related and associated with the ongoing operation and maintenance of an AAL solution are also to be included in this regard. These costs should be differentiated from personnel costs that are one-off costs, incurring e.g. during the installation or de-installation of an AAL product or service (see **investment, installation, and de-installation costs**).

Time of measurement:
The costs for operation and maintenance should be recorded for specific time intervals (e.g. month of commissioning) as well as for the total duration (based on OECD 2018:152).

Measurement mode:
Data should be requested from the AAL product or service providers, as they are most qualified to provide information on the respective prices or can draw on empirical values. Data can be collected in various ways, e.g. by paper or online questionnaires, telephone, or personal interviews (based on OECD 2018:218).

Further notes:
It must be clarified before and during the course of the project which operating materials and maintenance costs are to be recorded. Particularly in the case of operating materials, there is a possibility that these will be allocated to overhead costs since they are not clearly attributable. Therefore, care should be taken to avoid double counting and/or double billing.

Databases and cross-references to country-specific information:

European Union and EFTA

- Database - Labour Market (incl. LFS). (n.d.). Eurostat (see here: Earnings)
- Database - Purchasing power parities. (n.d.). Eurostat (see here: Purchasing power parities)

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Investment, Installation and De-installation Costs

Definition:
Investment and installation costs are defined as expenses for fixed assets such as machines, buildings but also initial equipment, spare parts, computer systems, etc. as well as associated installation costs (e.g. transport, assembly), which are usually one-off costs. De-installation costs are incurred after the service life when long-term assets are no longer needed (e.g. dismantling, removal, disposal).

Source of data:
R&D performing institution/company/product developers and secondary data and/or official statistic authorities

The cost or price of an AAL product or service includes all costs and follow-up costs incurred by the primary, secondary or tertiary user from the usage of an AAL product or service (based on Scharf et al. 2015:337). This measurement guide focuses on investment, installation, and de-installation costs.

In international comparative analyses, it is essential to consider the respective national purchasing power standard (PPS) as well as the corresponding Classification of Individual Consumption by Purpose (COICOP) in the analysis.

Object of measurement:
Investment, installation, and de-installation costs are a sub-category of capital expenditure or the machinery and equipment of the indicator (see **costs and revenues during development and market launch**).

It is necessary to record any costs for the delivery, assembly, installation, and de-installation (e.g. after the end of a project test phase or the decease of primary end-users) and to assess them at the purchase prices (excluding VAT, etc. where applicable) of primary, secondary or tertiary users monetarily (based on Kumpf et al. 2014:93).

Personnel costs associated with the installation and de-installation of AAL solutions are usually one-off costs and must be assigned to this category. Not included are personnel expenses that are attributed to current expenses (see **current expenses** in **costs and revenues during development and market launch).**

Time of measurement:
Investment, installation, and de-installation costs should be reported for the period in which they are incurred.

Measurement mode:
Data should be requested from providers of the AAL product or the AAL service, as they are most qualified to provide information about the respective costs. Data collection can take place in different ways, e.g. with a paper or online questionnaire, by telephone, or through personal interviews.

Databases and cross-references to country-specific information:

European Union and EFTA

- Database - Labour Market (incl. LFS). (n.d.). Eurostat (see here: Earnings)
- Database - Purchasing power parities. (n.d.). Eurostat (see here: Purchasing power parities)

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Market Potential

Definition:
The market potential is understood as the capacity of a market and the total possible sales volume of a market for a certain product or service. Market potential forms the upper limit for market volume.

Source of data:
Secondary data and secondary data and/or official statistic authorities

On the one hand, AAL technologies are characterized by push factors, in particular by technological progress and the associated development of new products and services. On the other hand, there are pull factors, above all the steady increase in the number of older people, which characterize this market (based on AAL Association 2014:8).

Due to these determinants, there is a very wide range of application areas and thus possible AAL solutions that attempt to increase or at least maintain the quality of life of older people. This results in a very indeterminate market term for AAL instead of a specific term, which can vary depending on the respective area of application of the solution and the therefore heterogeneous users, who differ e.g. in their health deficits. In particular, users influence the potential sales volume of an AAL solution, which needs to be defined in more detail in the next step.

Object of measurement:
Apart from the quantity sold, the possible number of consumers of AAL products and service solutions is one of the basic parameters for determining the market potential.

Consumers are further subdivided into primary users, i.e. people who benefit directly from AAL, secondary users, i.e. indirect users such as formal and informal health and care service providers, and tertiary users who do not use AAL directly but are involved in some way in its organization and financing (e.g. political decision-makers, representatives of social and/or private insurance companies). In the following, some measured quantities are presented that are either directly or indirectly relevant for determining the market potential.

Table 29: Measured quantities for determining market potential

Development of the AAL market
Current and potential users: Data on current and potential users (demographic data, user segments/profiles); socio-demographic indicators; socio-economic indicators; internet usage; technology orientation
Market value and size: intensity of usage; distribution rate; income and expenses; main benefits/problems
Market developments and driving forces: information on technology trends; emerging solutions (future products, forecasts, strategy plans, etc.); user perception; expectations; satisfaction
Interoperability and standardization issues: information on adopted/current standards
Development of key players
Number and type of key players and new market entrants: total; by market segment; by classification; by company size; business and marketing measures; sustainable business models; time to market
Development of investments
Number and type of market offensives: start-up companies; mergers and acquisitions; IPOs; support programs; survival rate of start-ups; investments by market segment/type of solution

Source: Based on AAL Association (2014:28); own representation

In addition to the number of potential users, the sales volume of an AAL solution depends primarily on the purchasing power of private and/or public households that pay for the financing of the solution.

In contrast to market potential, the market volume describes the units actually sold (sales) or the corresponding monetary measured values (turnover).

Time of measurement:
Market potential should be calculated for a full calendar year or at least for a precisely defined period of time (e.g. the next 5 years). In addition, the geographical coverage area (e.g. country, federal state) should be defined. This ensures comparability from both a temporal and a geographical perspective and makes the analysis of past and future trends possible.

Measurement mode:
Depending on the indicator chosen, different types of data, i.e. quantitative data, market research data, and qualitative data can be used to determine the respective indicator.

Official statistics and resulting quantitative data are usually of high quality and reliability. Often these are collected transnationally - especially in the European Union (EU) - according to uniform standards so that comparability between the countries is given. These data are particularly suitable for determining demographic trends, health expenditure as a percentage of the gross domestic product, etc. However, they are often not suitable for the analysis of innovative

markets, products, and product segments, which means that the characteristics of a market can only be inadequately represented.

To analyze these, quantitative market research data should therefore be used, but these are often only available to a limited extent and, above all, only against payment. With regard to the survey methods and associated data, it must also be noted that not the same quality criteria apply as, for example, to the national statistical offices.

Compared to quantitative surveys, qualitative surveys such as guided expert interviews, focus group interviews, case studies, etc. are often less structured, which is at the expense of the comparability of results. However, they offer solid and in-depth market information when a specific segment of customers, stakeholders, market scenarios (e.g. depending on socio-demographic characteristics), etc. is to be analyzed.

Databases and cross-references to country-specific information:

European Union and EFTA

- Database - Population and demography. (n.d.). Eurostat (see here: Population and demography)
- Database - Population projections. (n.d.). Eurostat (see here: Population projections)
- Database - Labour Market (incl. LFS). (n.d.). Eurostat (see here: Earnings)
- Database - Digital economy and society. (n.d.). Eurostat. (see here: Digital economy and society)
- Database – Structural business statistics. (n.d.). Eurostat. (see here: Structural business statistics)
- Database – Science and technology. (n.d.). Eurostat. (see here: Science, technology and innovation)

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Portugal (for country-specific information see page 68)

Romania (for country-specific information see page 71)

Slovenia (for country-specific information see page 74)

Spain (for country-specific information see page 77)

Switzerland (for country-specific information see page 80)

Avoided Resource Requirements

Avoided resource requirements are defined as cost reduction valued in the form of money.

Source of data:
Secondary data and/or official statistic authorities and/or electronic health records (EHRs)

This indicator focuses on the utilization of healthcare as well as formal and informal care and support services or the reduced utilization of the same as a result of the usage of AAL products and services and the (monetary) savings potentially associated with this. This applies, among others, to hospitals, ambulatory health care centers/health care providers (e.g. established general practitioners, specialists), and other health care professions (e.g. physiotherapists; based on OECD 2017:309-312).

Potential data sources are official statistics authorities (e.g., Eurostat), the Organisation for Economic Co-operation and Development (OECD), and the World Bank. The users can also provide an insight into the usage of health and care services via electronic health records (EHRs).

In the case of international comparative analyses, it is essential to take the respective national purchasing power standard (PPS) into account in the analysis.

Object of measurement:
Changes in the utilization of health care services can take place in natural units such as

- number of hospital days, number of discharges (for hospitals),
- number of respective services (for ambulatory health care centers and health care providers),
- number of consultations and treatment cases (for mobile nurses/caregivers and other health care professions).

The conversion of natural units into a monetary measured value is based on secondary data that quantify the respective average cost of a unit used.

Time of measurement:
The usage of health, formal and informal care and support services should be recorded, on the one hand, for specific time intervals (e.g. 4 weeks) and, on the other hand, at the beginning and end of an AAL project test phase (based on OECD 2018:152).

Measurement mode:
Data collection can take place through different modes, e.g. a paper or online questionnaire, by telephone, or even personal interviews (based on OECD 2018:218). Data should be requested from the respective health service providers or collected from the users. Data provision should be anonymized and, if possible, provided in aggregated form for both the intervention and a control group.

Databases and cross-references to country-specific information:

European Union and EFTA

- Database - Labour Market (incl. LFS). (n.d.). Eurostat (see here: Earnings)
- Database - Purchasing power parities. (n.d.). Eurostat (see here: Purchasing power parities)
- Database - Health. (n.d.). Eurostat (see here: Health)
- OECD Health Statistics 2021 - OECD. (n.d.). OECD (see here: OECD Health Statistics)
- Health Nutrition and Population Statistics | DataBank. (n.d.). World Bank (see here Health Nutrition and Population Statistics)

Austria (for country-specific information see page 42)

- Electronic health records, i.e., Elektronische Gesundheitsakte (see here: ELGA)

Belgium (for country-specific information see page 45)

- Electronic health records, i.e., Summarized Electronic Health Record (see here: SUMHER)

Cyprus (for country-specific information see page 48)

Hungary (for country-specific information see page 50)

- Electronic health records, i.e., Elektronikus Egészségügyi Szolgáltatási Tér (see here: EESZT)

Italy (for country-specific information see page 53)

- Electronic health records, i.e., Fascicolo Sanitario Elettronico (see here: Fascicolo Sanitario Elettronico)

Luxembourg (for country-specific information see page 56)

- Electronic health records, i.e., Dossier de soins partagé (see here: DSP)

Netherlands (for country-specific information see page 59)

- Electronic health records, i.e. Persoonlijke gezondheidsomgeving (see here: PGO)

Norway (for country-specific information see page 62)

- Electronic health records, i.e., Digital Health Services (see here: HELSENORGE)

Poland (for country-specific information see page 65)

- Electronic health services and records, i.e. E-usługi (see here: E-usługi)

Portugal (for country-specific information see page 68)

- Electronic health records, i.e., ePortugal (see here: ePortugal)

Romania (for country-specific information see page 71)

- Electronic health records, i.e., Dosarul Electronic de Sănătate (see here: DES)

Slovenia (for country-specific information see page 74)

- Electronic health records, i.e., zVEM (see here: zVEM)

Spain (for country-specific information see page 77)

- Electronic health records, i.e., É-Saúde (see here: É-Saúde)

Switzerland (for country-specific information see page 80)

- Electronic health records, i.e., Elektronisches Patientendossier (see here: EPD)

2.3. Application Example Health: AAL Pilot Region Smart VitAALity

Brief description of the AAL solution:[3] Within the AAL pilot region Smart VitAALity, an integrated AAL system in the smart city setting "Health, Inclusion and Assisted Living" is evaluated in about 100 senior households. The project aims at a needs-oriented and theory-driven technology development, multidimensional evaluation, and a derived sustainability strategy. From a functional point of view, the system is adapted to the users and their environment, intuitively usable, and well integrable into already existing everyday processes. The service aims at long-term preservation of quality of life and its dimensions (health, social inclusion) as well as at a positive influence on subjective well-being.
The Smart VitAALity system consists of various technical components that support seniors in their everyday lives, thus increasing their quality of life. The functions can be divided into the following three major areas:

- health management
- social inclusion and participation
- well-being and safety in everyday life

The technology package consists of modern communication and information technologies such as smartwatches and tablets, sensor technology, and measuring devices for vital parameters (body scales, blood pressure, and blood glucose). Based on a state-of-the-art (SOTA) analysis, the system's individual components were tested for their functional scope and selected. The Smart VitAALity system is tested in 100 households in the urban triangle "Klagenfurt - Villach – Ferlach" and evaluated by the test persons. In addition, there is a control group without a technology package (in over 100 households) in order to be able to draw comparisons. The different city sizes (from 10,000 to 100,000 inhabitants) offer the study a space that is representative of Austria's urban landscape and at the same time enables comparisons to be made in different urban structures.
The test persons are senior citizens aged between 60 and 85 years (or individuals with geriatric diseases from 55 years) who live independently with the need for support in a household (up to care level 4).

All 100 test households are equipped with a homogeneous system. This means that each test person receives identical hardware and software components for the pilot phase. In addition to personal training, technical support is provided via a support hotline, and meetings are held regionally to exchange information and accompany the test phase.

[3] Oberzaucher, J. (2017); Smart VitAALity pilot region; http://www.aal.at/pilotregionen-3/vitaality/

Project data:

Duration:	01 January 2017 – 31 December 2019
Funding authority:	Federal Ministry for Climate Action, Environment, Energy, Mobility, Innovation and Technology (BMK, formally known as BMVIT)
Program management:	Austrian Research Promotion Agency (FFG)
Program:	ICT of the future: benefit – Opportunity through demographic change
Project management:	FH-Prof. DI Dr. Johannes Oberzaucher
Project partners:	Carinthia University of Applied Sciences non-profit private foundation (project management) Joanneum Research Forschungsgesellschaft mbH ilogs mobile software GmbH Hilfswerk Kärnten (Carinthia aid organisation)

The functions and equipment of Smart VitAALity are intended to contribute to maintaining or, if necessary, improving the physical, mental and social well-being of people who are getting older. For this reason, individuals aged 60 to 85 years who live independently or with little need for support in a household (up to care level 4) were selected during recruitment in both the intervention and control groups. Since the measurement of body and vital data, the diagnosis and maintenance of health are in the foreground, this AAL product is assigned to the application area of “health”. Accordingly, the non-reactive data described below are relevant for the evaluation. As can be seen in Table 30, a lead time (project months 1 to 12) of one year is planned for the development and conception of the project before the field test (project months 13 to 30), and a follow-up time (project months 30 to 36) of six months for the evaluation and dissemination of the project. Depending on the respective indicator, the determination of the same takes place in the field test phase, the lead time, or the follow-up time, as shown in the table. The following paragraphs provide more detailed information on the specific indicator.

Within the framework of the implementation of the AAL pilot region Smart VitAALity, **investment, installation and de-installation costs** arise due to the implementation of the Smart VitAALity system, which is usually one-off costs incurred in the initial project phase. These include the purchase of technical equipment (investment; project months 1 to 12) and the installation in the participating 100 test households (set-up and training; project months 13 to 15). At the end of the field test, possible de-installation costs due to the dismantling of the Smart VitAALity system should also be taken into account (e.g. disassembly and removal; project months 28 to 30). **Human assistance costs** (for training, support, and services for primary users), as well as expenses for operating materials and maintenance costs (technical operating costs (e.g. electricity), repair and maintenance services, insurances, etc.), represent running costs that need to be paid and recorded at regular or irregular intervals (project months 13 to 30).

Table 30: Proposal for the temporal determination of the parameter collection in Smart VitAALity

Project month	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**	**21**	**22**	**23**	**24**	**25**	**26**	**27**	**28**	**29**	**30**	**31**	**32**	**33**	**34**	**35**	**36**
Evaluation phase:	**Lead time**												**Field phase**																		**Follow-up time**					
Investment costs	■	■	■	■	■	■	■	■	■	■	■	■																								
Installation costs													■	■	■																						
De-installation costs																												■	■	■						
Human assistance costs													■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■						
Operating materials and maintenance costs													■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■						
Personnel costs (costs and revenues during development and market launch)	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■
Avoided resource requirements													■	■	■													■	■	■						
Consideration of ethical guidelines	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■
State of health (reactive)													■	■	■													■	■	■						
State of health (non-reactive)													■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■						
Active/Passive usage													■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■						
Error data							■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■						
Market potential																										■	■	■	■	■	■	■	■	■	■	■

Source: own representation

All expenditures for tangible investments (tablets, smartwatches, sensors, operating materials (e.g. electricity), etc.) are recorded at the purchase prices of the respective point in time (invoice date) without taking into account the deductible percentage of VAT and similar taxes. Installation, de-installation, and maintenance are primarily personnel-intensive services, which is why the number of hours required per household as well as the hourly rate paid to employees (incl. any overhead costs) are documented by the executing institution (e.g. Carinthia University of Applied Sciences). Any personnel costs that contribute directly to the research and (further) development of the AAL solution to be evaluated must be distinguished from personnel expenses incurred. These personnel costs must be added separately to the personnel costs of ongoing R&D expenses, which could prove difficult in everyday project life. Alternatively, it should be considered to deduct personnel costs incurred for installation, maintenance, etc. from the total personnel costs and allocate the resulting difference to **personnel costs for research and development** (costs and revenues during development and market launch). Personnel costs are recorded over the entire period of the project (project months 1 to 36).
The health management functions of Smart VitAALity are expected to result in lesser resource requirements and a reduction of the utilization of general practitioners, internists, outpatient clinics and hospital visits. In order to sufficiently test this hypothesis, it is recommended to record the utilization of selected health services as well as formal and informal care and support services for certain time intervals (e.g. four weeks) at the beginning (project months 13 to 15) and at the end (project months 28 to 30) of the field test in natural units (e.g. number of consultations with the general practitioner). Documentation takes place in test households where the AAL solution is installed as well as in control households where no change has been made. Finally, the results of the groups are compared and checked for significant differences and, based on data from official statistics (e.g. average costs of a doctor's visit), converted into monetary units or the lower resource consumption estimated.
The **consideration of ethical guidelines** must already take place when writing the project application and throughout the entire duration of the project. This includes, especially in the initial phase (project months 1 to 14), obtaining a declaration of consent from the responsible ethics committee, if necessary, and the recruited participants' targeted information. This includes information about project goals, potential benefits, duration of the field test, time schedule, planned qualitative and/or quantitative surveys, voluntary participation, and possibilities of opting out of the project. Confirmation of the explicit information on applicable framework conditions is made in writing by signing the informed consent before project testing in the households. This informed consent must be guaranteed and communicated throughout the entire duration of the project.
The **health status** of the test households should be determined immediately before the installation (project months 13 to 15) and after the dismantling (project months 28 to 30) of the AAL components in the households by means of validated questionnaires (e.g. EvAALuation² questionnaire, EQ-5D, WHOQOL BREF). In order to prove the effectiveness of the system, the same questionnaires must also be completed by the control group at approximately the same time interval.
Equipping the test households with body scales, blood pressure monitors, blood glucose monitors, and smartwatches offers the opportunity to collect many vital parameters during the entire

field test, which allows conclusions to be drawn about the state of health and its development (project months 13 to 30).
In the Smart VitAALity pilot region, **active usage** of the AAL components is defined by the project team as when the participants use the apps on the tablet, e.g. to chat with other participants, play games, view health data, or look at the weather forecast. The steps that the participants take every day are **passively** counted using a smartwatch. In addition, movement sensors in the living rooms and a sensor on the refrigerator passively collect data on the behavior of users. The collection of usage data happens automatically through logging. The evaluations of this active and passive usage during the field test (project months 13 to 30) allow conclusions to be drawn about the usefulness and user-friendliness.
The project team tests the system functions with test persons in a laboratory setting and analyses (subjective and objective) error data before the roll-out (project months 7 to 12). After the installation of the AAL solution, participants reach the helpdesk by telephone in case of problems and, if necessary, staff members are sent on-site to solve the problem. In this regard, it is recorded which errors occur how often during the field test and how much time the respective service visits take (project months 13 to 30).
The **financial burden for end users** depends on the implementation of the AAL solution. The research project allows an approximate calculation of the costs for the primary/secondary/tertiary users in case of a market introduction. If possible, the end users' marginal willingness to pay could be collected in the reactive survey described below in order to be able to draw conclusions through linkage with other indicators.
The market potential should be determined in the last year of the project (project months 25 to 36) because it can be assumed that the first results of the acceptance analyses of Smart VitAALity will already be available by then. Such analyses make it possible to revise the system if necessary, i.e., reduce or expand it by certain functions to advance market maturity. The market volume can be estimated by linking the willingness to pay with socio-economic data (e.g. purchasing power).

For the reactive data, the use of the **questionnaire for the application area health** is proposed. These include the following indicators or subscales:

- Subjectively relevant activity level
- Autonomy & self-determination
- Life & health satisfaction
- Age(ing)-related self-image
- Health-promoting behavior
- Social interaction
- Social participation
- Access & offer healthcare
- Affordability of healthcare
- Services used (health care system)
  Care and support needs
- Therapy adherence/-compliance

- Willingness to pay
- Subjective intention of use
- Pragmatic user experience
- Stigma-free design
- Hedonic user experience
- Freedom of choice regarding service access
- Privacy

Since a control group is planned, both a pre-post comparison and a comparison with the control group can be made. For the control group as well as for the determination of the baseline of the experimental group, i.e. the values before the installation of the AAL solution, all items with technology reference (i.e. the operationalizations willingness to pay, freedom of choice regarding service access, subjective intention of use, hedonic and pragmatic user experience, stigma-free design and privacy from the user's perspective) should be removed from the questionnaire as they cannot be answered by the participants.
Furthermore, additional survey dates are also conceivable: For example, for the baseline, the average of two points in time, e.g. M8 and M10, can increase data quality, since the influence of situational circumstances can be minimized. The additional use of the entire questionnaire for the experimental group and the technology-free version for the control group during the field phase (e.g. after one, three, six, twelve, etc. months) can provide insights into changes over time. After major updates of the solution, the usage is also conceivable, e.g. when errors have been fixed, to understand how these had affected the intended effects. In this way, it can be taken into account that evaluations of AAL solutions are usually not linear since solutions are often revised during the field phase on the basis of user feedback. In any case, the questionnaire should be made available identically to all participants in order to keep possible methodological effects constant (e.g. anonymity may be perceived differently depending on the mode). A simply designed online questionnaire suitable for a large number of people with different technology competencies, or paper questionnaires, for example, summarized in a book for the entire duration of the study, would be conceivable in the Smart VitAALity pilot region. However, it must be ensured that all test persons complete the questionnaires at the same time during the study. The evaluation can then be made by group comparisons (control group vs. experimental group; pre vs. post) or interferential statistical analyses (e.g. regression analyses).

3. Care

In the following, the measuring instruments developed to evaluate the effects of AAL solutions in the area of care are presented.
This implies technologies that aim at maintaining or improving the quality of life of people in care. The target population comprises the users of these solutions. The reactive and non-reactive measuring instruments are based on the gathering of indicators which are summarised below. In addition, it is pointed out whether the respective indicator is to be collected reactively or non-reactively as well as the definition of the indicator and the source(s) that were incorporated into the creation of the operational definition. By clicking on "reactive" or "non-reactive" you can switch directly to the operationalization.

Vitality and Quality of Life Goals

Maintaining, expanding, or improving skills and independent activities:

Subjectively relevant activity level (reactive): Self-performance of activities that contribute to the well-being and are experienced as meaningful. This applies in particular to activities that contribute to maintaining or improving health and life satisfaction (based on Orem 2001; Pratt & Ashforth 2003; Diener, Emmons, Larsen & Griffin 1985).

Cognitive and mental abilities (reactive): The person's self-perceived abilities that relate to perception, thinking, or cognition and serve to fulfill subjectively relevant activities (based on Kent 2006s; Kaminski & Neisser 1994; Zimbardo 1995; Tuomi et al. 1998).

Physical abilities (reactive): Self-perceived physical abilities to perform subjectively relevant activities (based on Kent 2006b; Martin 2015).

Maintaining or improving well-being:

Autonomy & self-determination (reactive): Autonomy is the self-determined making of decisions. The following is subsumed under perceived self-determination: knowing the subjective degree of freedom from (1) obstacles, (2) possibilities of action, (3) choosing possibilities of activity, (4) acting (carrying out activities), and (5) the freedom to create new possibilities of activity for oneself. Self-assessment of opportunities for action concerns (1) overall assessment, (2) subjectively relevant activities, and (3) activities that promote health (based on Thomasma 1984; Mittelstadt, Fairweather, McBride, & Shaw 2011).

Age(ing)-related self-image (reactive): The age(ing)-related self-image is an evaluative assessment based on proactive analysis of oneself and interaction partners about oneself and one's own age (own development).

Maintaining or improving health:

Life & health satisfaction (reactive): Life satisfaction refers to an internal norm that is formed in comparison with the social environment and one's own ideals/goals. This concerns both the specific health situation and one's own life as a whole (based on Diener, Emmons, Larsen & Griffin 1985; Frieswijk, Buunk, Steverink & Slaet 2004). Health is de-

fined as an ideal-typical positive functional overall condition with bio-psycho-social aspects, which is realized along a continuum to the construct “illness”. The subjective state of health is defined as a momentary perception and evaluation of one’s own health. It is functional in general as well as with regard to meaningful activities (based on Hilfebrandt & Kickbusch 2000; Reichard, Alricsson & Werner 2008; Silva et al. 2018; Lawton & Brody 1969).

Health-promoting behavior (reactive): Health-promoting behavior refers to behavior that is related to maintaining, restoring, and improving health. The adoption of these measures refers to the attitude and actions with which the individual approaches these measures, and is particularly evident in goal-oriented actions or refraining from actions (e.g. health information seeking) (based on Zielegmann 2002; Graffigna et al. 2017; Lawton & Brody 1969).

Social Goals

Promotion of inclusion and participation:

Social interaction (reactive): Social interaction denotes interrelated actions of two or more individuals, e.g. in the form of linguistic communication. Particularly, the focus is on satisfaction with the frequency of interaction, the number of social contacts, and the quality of the interaction (based on Brockhaus Enzyklopädie 1989:560).

Social participation (reactive): Social participation is defined as the degree of subjective participation in society in the sense of a sense of belongingness, participation in subjectively relevant social activities, and the necessary resources and opportunities (based on UNECE 2010:2).

Consideration of ethical criteria during development and implementation:

Consideration of ethical guidelines (non-reactive): The consideration and evaluation of moral actions during the development and use of products and services included, among other things, informed consent, a benefit-risk assessment, and risk minimization measures (based on Gabler 2019).

Freedom of choice regarding service access (reactive): Freedom of choice regarding service access includes the degree of perceived self-determination during the usage of AAL products and services (own development).

Freedom of stigma (reactive): The term “stigma-free” refers to the perceived degree of absence of negative categorization and discrimination based on specific characteristics or attributes that arise from the usage of an AAL solution. This particularly concerns negative attribution due to age(ing) and associated negative stereotypes (based on Goffman 1963; Link & Phelan 2001).

Social System Goals

Improving the Care and Support System:

Care and support needs (reactive): The care and support effort is defined by the hours of care provided by formal and informal caregivers, which is carried out in person or virtually (based on Wingenfeld 2014:263-290).

Access to and offer of healthcare (reactive): Access to and offer of care and support services is defined by physical accessibility and acceptance of these. Physical accessibility refers to the availability of care services within a reasonable distance and with suitable opening hours. (based on WHO 2016).

Affordability of healthcare (reactive): Financial affordability means the care or support service can be paid for without much difficulty, which depends, among other factors, on the health financing system and household income. Acceptance concerns people's willingness to make use and pay for the offers. Acceptance is low when people perceive the services as ineffective or when social and cultural factors such as age, gender, ethnicity, religion of the service provider discourage people from using the service (based on WHO 2016).

Services used (health care system) (reactive): This refers to the use of services of the health care system (inpatient and outpatient sector), medication consumption, and preventive health care (own development).

Care and support quality (reactive): Measurable changes in the satisfaction of patients or their relatives as a result of framework conditions and measures (based on Gesundheit Österreich GmbH 2013:108).

Improvement of the health care system:

Therapy adherence/compliance (reactive): Adherence refers to the extent to which a person's behavior, including medication intake, a diet regime, or lifestyle changes, conforms to the recommendations arranged with the therapist (based on WHO 2003).

Establishment and exploitation of the market potential:

Costs and revenues during development and market launch (non-reactive): Costs are defined as the use or consumption of production factors valued in the form of money (e.g. quantity of input factors or time), which arises within a certain period of time (e.g. months or years). The term "revenues" denotes the generation and utilization of goods and services within a specific accounting period that is performance-related and valued in the form of money (based on Hoitsch & Lingnau, 2002:16; von Känel 2008:22).

Market potential (non-reactive): Market potential is defined as the capacity of a market and the total possible sales volumes of a market for a specific product or service. The market potential forms the upper limit for the market volume (based on Gabler 2018, online).

Willingness to pay (reactive): This refers to the maximum price at which a consumer is willing to buy a unit of a good (based on Jedidi & Jagpal 2009:40).

Business feasibility:

Investment, installation, and de-installation costs (non-reactive): Investment and installation costs include costs for the usage of longer-term assets such as machines, buildings, but also for initial equipment, spare parts, computer systems, etc. De-installation costs arise after the end of use of the longer-term assets when they are no longer needed (based on Gabler 2018).

Operating materials and maintenance costs (non-reactive): Operating and maintenance costs refer to the consumption of raw materials, auxiliary and operating materials, externally sourced primary products as well as personnel costs for the operation and maintenance of AAL products and components that are valued in the form of money. A distinction is made between performance-variable direct and overhead costs and performance-fixed costs (based on von Känel 2008:150).

Human assistance costs (non-reactive): Human assistance costs refer to the consumption of raw materials, auxiliary and operating materials, externally sourced primary products, and personnel costs for human assistance in the usage of AAL products and components that are valued in the form of money. This includes, among other things, user training as well as support and service information. A distinction is made between performance-variable direct and overhead costs and performance-fixed costs (based on von Känel 2008:150).

Financial burden for users (non-reactive): Periodised expenditure valued in the form of money of a primary, secondary or tertiary user in a periodized accounting period for the usage of AAL products and components (based on Gabler 2018).

Overall economic, financial sustainability:

Avoided resource requirements (non-reactive): Avoided resource requirements are defined as the reduction of costs valued in the form of money in the health care sector within an accounting period in comparison to a reference condition (e.g. without and with the use of AAL products) (own development).

Design and Technology Goals

Acceptance and user experience:

Subjective intention of use (reactive): Subjective intention of use is the behavioral intention of a person to actually use a specific AAL solution for a purpose envisaged in its development (based on Davis, 1989; Venkatesh & Bala 2008).

Pragmatic user experience (reactive): User experience is defined as the evaluative perception of an AAL solution by a person resulting from the use and/or the expected use of a system. It concerns functional aspects, especially perceived usability and usefulness (based on ISO 9241-210:2010; Hartsin & Pyla 2012; Raisamo et al. 2012).

Hedonic user experience (reactive): User experience is defined as the evaluative perception of an AAL solution by a person resulting from the use and/or the expected use of a system. The hedonic level especially concerns the emotional impact (based on ISO 9241-210:2010; Hartsin & Pyla 2012; Raisamo et al. 2012).

Stigma-free design (reactive): Freedom of stigma refers to the perceived degree of absence of negative categorization and discrediting based on specific characteristics or attributes that arise from the usage of an AAL solution. This particularly concerns negative attribution due to age(ing) and related negative stereotypes (based on Goffman 1963; Link & Phelan 2001).

Active/Passive usage (non-reactive): Active usage is defined as usage during which users consciously interact with a system (voluntary and controlled input or output). Passive usage is defined as usage during which users do not consciously interact with the system even though it is active (own development).

Safe handling and protection of data:

Privacy from user perspective (reactive): Privacy from the user's perspective concerns the individual perception of the extent of control over data that the user considers to be personal data. This relates to risk assessments of unauthorized access, unauthorized re-use, concerns that protection against intentional and accidental errors is inadequate, and the extent of data collection (based on Smith, Milberg & Burke 1996; Clarke 1999; Ackerman & Mainwaring 2005; Bélanger & Crossler 2014).

Quality of the technical solution:

Error data (non-reactive): An error is an unexpected system status that results in the inability to perform an intended function. An error can be software-related or hardware-related (based on Butterfield & Ngondi 2016a; Butterfield & Ngondi 2016b).

3.1. Questionnaire Instrument for Users of AAL Solutions (Reactive Data Collection)

Notes on the use of questionnaires and the avoidance of process errors

The questionnaire was constructed for usage with older users whose health shall be maintained or improved with the help of the AAL solution. It takes about 20 minutes to answer the full questionnaire which can be classified as adequate for the target group. The questionnaire was constructed for written surveys (paper or digital) for independent interviewing. If the questionnaires are used in contexts where researchers or examiners are present, they should keep their distance in order to signal to the respondents that they do not look at their answers. If questions arise, for example, due to comprehension problems, the examiners should react with as much reserve as possible, suggest to the test persons that there are no wrong answers and, in case of doubt, only paraphrase the formulations. However, they should certainly not suggest answers so as not to influence the results. The layout of the questionnaires should be kept constant at all survey times and illustrations should be avoided. In the case of oral questioning, the answer items should be read aloud, whereby in the case of scales all answer points should be verbalized at least once, and at least the endpoints and the number of points should be mentioned. The possibility of answers is thereby put in front of the first question with the explanation that the respondent should rate the following statement (for the first question: "On a scale of one to five, where one means 'do not agree at all', two means 'rather disagree', three means 'neither', four means 'rather agree' and five means 'completely agree', how would you rate the following statements:"; and then: "On a scale of one to five, where one means 'strongly disagree' and five means 'strongly agree', how would you rate the following statements:"). We

recommend giving preference to written survey modes. However, in any case, make sure that the mode is not varied over different survey times.
The questionnaire captures the subjective assessment of older users of the status quo or, in the case of retrospective questions, of the last four weeks prior to the time of the survey. It is, therefore, suitable for a variety of research designs and allows, for example, to measure effects over time or to make comparisons with a control group. The measurements of the fulfillment of design and technology goals as well as the items on willingness to pay and freedom of choice regarding service access, which are not presented in the case of (as yet) non-existent technology usage (e.g. control group, measurement of the baseline in the case of pre-post designs), form an exception here.

Instructions for the participants on answering the questions

General instruction

Thank you very much for participating in this survey.
We would like to ask you to complete the following questionnaire. The questions relate to your personal assessments of your health, your well-being, of health care and care situation as well as your approach to digital technologies in general and to *<technology>* in particular.
It takes about 20 minutes to complete the questionnaire. Please make sure to answer all questions. Please read each question carefully before answering. There are no right or wrong answers. If you have any questions about this questionnaire, please contact the examiner in charge.

Interim instructions

The scale “Subjectively relevant activity level“ is introduced with the following instruction: The following questions refer to your general and health-related well-being. Now please think of activities in your life that you personally feel are particularly important, that do you good or that you experience as meaningful. Write down three such activities in the corresponding “activity” fields and then rate the statements for each activity.
Items “Access & offer healthcare”, “Affordability of healthcare”, “Care and support needs” “Services used (health care system)”, and “Therapy adherence/-compliance are introduced with the following instruction: The following deals with care and support services (e.g. care and support both at home and in a residential or care facility; daycare or counseling and therapy).

Items

Table 31: Items of the instrument for the evaluation of AAL technologies in the areas of care & support

No.	Item	Subscale
SRA1	I am satisfied with the degree to which I can carry out the activity myself.	Subjectively relevant activity level
SRA2	I am satisfied with my mental abilities to carry out the activity.	Subjectively relevant activity level
SRA3	I am satisfied with my physical abilities to carry out the activity.	Subjectively relevant activity level
AS1	I can make self-determined decisions in my life.	Autonomy & self-determination

No.	Item	Subscale
AS2	I can decide for myself which activities that are important to me personally I undertake.	Autonomy & self-determination
AS3	I can decide for myself which activities of daily living (eating, body care, dressing) I undertake.	Autonomy & self-determination
LHS1	Concerning my physical abilities, I feel rather...	Life & health satisfaction
LHS2	Concerning my mental abilities, I feel rather...	Life & health satisfaction
LHS3	Concerning my social well-being, I feel rather...	Life & health satisfaction
LHS4	I am generally satisfied with my life.	Life & health satisfaction
LHS5	When I think of my ideals and goals, I am satisfied with my life.	Life & health satisfaction
LHS6	Compared to other people around me, I am satisfied with my life.	Life & health satisfaction
LHS7	When I think of my ideals and goals, I am satisfied with my care situation.	Life & health satisfaction
LHS8	Compared to other people around me, I am satisfied with my care situation.	Life & health satisfaction
ARSI1	Compared to my age in years, others perceive me as young.	Age(ing)-related self-image
ARSI2	Compared to my age in years, I perceive myself as young.	Age(ing)-related self-image
ARSI3	I like being as old as I am.	Age(ing)-related self-image
HPB1	I consciously take actions that promote my health (e.g. sports or healthy eating).	Health-promoting behavior
HPB2	I consciously refrain from actions that are harmful to my health (e.g. smoking).	Health-promoting behavior
HPB3	I inform myself about what behavior is considered healthy or harmful to health.	Health-promoting behavior
SI1	I am satisfied with the frequency with which I am in contact with other people.	Social interaction
SI2	I feel part of society.	Social interaction
SI3	I am satisfied with the number of people I am in contact with.	Social interaction
SP1	I have the opportunity to participate in social activities that are important to me.	Social participation
SP2	I am satisfied with the quality of interaction with my personal contacts.	Social participation
SP3	I feel like I belong to a group (e.g. neighborhood, family, sports club).	Social participation
AOH1	I am satisfied with the availability (e.g. opening hours, distance) of health services.	Access & offer healthcare
AH2	I am willing to make my financial contribution for services.	Affordability of healthcare
AH3	Necessary health services are easily financeable for me.	Affordability of healthcare
AOH5	I am satisfied with the quality of the care and support I receive.	Access & offer healthcare
SU1	I have used services (e.g. doctor's visit, prescriptions, inpatient or outpatient stay) in the last four weeks.	Services used (health care system)

No.	Item	Subscale
SU2	What services exactly?	Services used (health care system)
CSN1	In the past four weeks, I have received care and support from professional caregivers who are present, in the amount of about (hours):	Care and support needs
CSN2	In the past four weeks, I have received care and support from relatives or acquaintances, in the amount of about (hours):	Care and support needs
TAC1	I adhere to the agreement concerning my health-related behavior I have made with my doctor (e.g. intake of medication, diet, lifestyle).	Therapy adherence/-compliance
TAC2	My doctor thinks that I am adhering to the agreed health-related behavior.	Therapy adherence/-compliance
CSN1	In the past four weeks, I have received care and support from professional caregivers who are present, in the amount of about (hours):	Care and support needs
CSN2	In the past four weeks, I have received care and support from relatives or acquaintances, in the amount of about (hours):	Care and support needs
WTP1	Now think of <technology>, at what purchase price would this product be too expensive for you (in Euro)?	Willingness to pay
SIU1	How often will you use <technology> next year?	Subjective intention of use
PUX1	The usage of <technology> is simple.	Pragmatic user experience
SFD7	<technology> emphasize my weaknesses.	Stigma-free design
SFD1	When I use <technology>, I feel old.	Stigma-free design
HUX1	I enjoy using <technology>.	Hedonic user experience
SFD3	People around me perceive me as old when they learn that I use <technology>.	Hedonic user experience
HUX1	I like using <technology>.	Stigma-free design
PUX2	The usage of <technology> supports me in my daily life.	Pragmatic user experience
SFD5	I think that people see me in a different, worse light when they learn that I use <technology>.	Stigma-free design
SFD6	I do not want others to know that I use <technology>.	Stigma-free design
PUX3	<Technology> are useful to me.	Pragmatic user experience
SFD4	I am ashamed to use <technology>.	Stigma-free design
FC1	I can decide for myself whether I use <technology>.	Freedom of choice regarding service access
FC2	I can decide for myself how often I use <technology>.	Freedom of choice regarding service access
PR1	It is likely that someone accesses my <technology> data without permission.	Privacy
PR2	It is likely that someone uses my <technology> data without permission for purposes with which I disagree.	Privacy
PR3	It is likely that my <technology> data is not sufficiently protected due to an error.	Privacy

Answer specifications
Five-point response format with the options 1 = strongly disagree, 2 = rather disagree, 3 = neither, 4 = rather agree, 5 = strongly agree
Exceptions:

- Items LHS1, LHS2, LHS3: Five-point response format with the options 1 = sick to 5 = healthy
- Item WTP1: From a purchase price of ___ euros
- Item SIU1: Six-point response format with the options 1 = never, 2 = less often than once a month, 3 = monthly, 4 = weekly, 5 = daily, 6 = several times a day
- Item SU3: open (text)
- Items CSN1, CSN2: open (numbers)

Evaluation notes
In the questionnaire instrument, the respective indicators are operationalized by single or multiple items. For the individual items, we recommend calculating mean values or comparing the absolute numbers. In principle, high values stand for strong agreement and low values for weak agreement.
For indicators that are measured by several items (scales), scale averages are to be formed. Thereby the response values of the assigned items are added up and divided by the number of items. For example, for the scale *autonomy and self-determination*, the values of the items AS1, AS2, and AS3 are added together and then divided by three. The following list shows all items per multi-item subscale:

- Access & offer healthcare: AOH1, AOH5
- Affordability of healthcare: AH2, AH3
- Age(ing)-related self-image: ARSI1, ARSI2, ARSI3
- Autonomy & self-determination: AS1, AS2, AS3
- Freedom of choice regarding service access: FC1, FC2
- Health-promoting behavior: HPB1, HPB2, HPB3
- Hedonic user experience: HUX2, HUX3
- Life & health satisfaction: LHS1, LHS2, LHS3, LHS4, LHS5, LHS6, LHS7, LHS8
- Pragmatic user experience: PUX1, PUX4, PUX5
- Privacy: PR1, PR2, PR3
- Social interaction: SI1, SI2, SI3
- Social participation: SP1, SP2, SP3
- Stigma-free design: SFD1, SFD3, SFD4, SFD5, SFD6, SFD7
- Subjectively relevant activity level: SRA1, SRA2, SRA3
- Therapy adherence/-compliance: TAC1, TAC2

In general, missing values should be avoided in the survey. In the case of an online survey, it is recommended to make answering the items compulsory. Furthermore, we recommend that

an evaluation is only carried out when at least three questionnaires have been completed in order to avoid violation of anonymity. It must be noted that the principal component analyses showed several cross-loadings occurred. However, these cross-loadings are in line with the definitions of the indicators, but we recommend calculating intercorrelations of the respective scales. Furthermore, we want to draw attention to the item PUX1 whose item-total correlation is beyond the threshold of .300. The item was not deleted due to relevance to the construct (ease of use for pragmatic UX). However, we recommend rechecking the reliability of the scale before analysis.

Furthermore, we removed two scales the items SRA4-9 of subjectively relevant activities due to diffuse component loadings. We assume that the subjective relevance and quality of the specific activities vary too much to include them in one scale. We, therefore, recommend not including activity 2 (SRA4-6) and activity 3 (SRA7-9) in the scale values, but descriptive analyze these items. Nonetheless, these items may be useful to gain better insight as it is highly unlikely that older people receiving care or support consider only one activity alone to be central.

3.2. Collection of Key Figures (Non-reactive Data Collection)

Consideration of Ethical Guidelines

Definition:
The consideration and evaluation of moral actions during the development and usage of products and services include, among other things, informed consent, a benefit-risk assessment, and measures to minimize risk.

Source of data:
R&D performing institution/company/product developers

The developers or project teams can provide insight into the extent to which ethical guidelines are taken into account in developing and using AAL products and services. The following definition is used for the term ethics (Gabler 2019): “Ethics is the doctrine or theory of action according to the distinction between good and evil. The subject matter of ethics is morality. Greek ethics was empirical and normative at the same time. Today, empirical, descriptive ethics is strictly distinguished from normative ethics, which formulates an ought; this ought makes a claim to be generally binding.”

Object of measurement:
The compliance with ethical guidelines in the development and use of products and services in the field of AAL is measured, taking into account the special needs of older people. At this point, it should be mentioned that this is not exclusively a technology goal, but that exit strategies and similar ethical considerations must also be included.

The following questions can be helpful for the assessment of compliance with ethical guidelines (Felnhofer et al. 2013):

- **Recruitment of participants:**
  - Was the aim of the study explained during recruitment?
- **Benefit-risk assessment:**
  - Have potential risks been identified?
  - Have all steps been taken to minimize the risks?
  - Do the benefits justify the risks?
- **Informed consent:**
  - Was informed consent (IC) given?
  - Did the IC include the following points:
    - aim of the survey
    - duration and procedure of the survey
    - indication of the voluntary nature of participation

        - indication of the possibility to opt-out of the survey at any time and, if so, how to do this
        - explanation of benefits
        - indication of risks
        - contact for further queries
    - Is the information formulated in a comprehensible way and formatted in an age-appropriate way?
    - Has a consent form been signed?
- **Exit strategies**
    - Are there considerations on how to end the project?
    - Is the sustainability of the project ensured beyond its duration?
- **Ethics committee**
    - Has an ethics committee approved the project?

Time of measurement:
Ethical questions must already be clarified or taken into account during the planning or development of AAL products and services. At the latest, however, before the practical application on humans, it should be possible to answer the issues mentioned positively before the test phase.

Measurement mode:
An interrogative process with the help of guidelines as well as codes can accompany the consideration of ethical guidelines. In this context, checklists (see e.g. Felnhofer et al. 2013) can have a supportive effect.

Further notes:
Is there a manual that describes the entire development process and includes ethical considerations?

Another useful tool to include ethical considerations in the development process can be the Gender Sensitive Research Cycle (European Commission DG Research & Innovation 2011:14). The approach is twofold, on the one hand involving men and women equally and thus creating equal opportunities. On the other hand, this approach includes “gender” from the beginning to the end, from the project idea to the publication of the results.

Databases and cross-references to country-specific information:

European Union

- Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (Text with EEA relevance, here: Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (Text with EEA relevance)
- Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC Text with EEA relevance (European Parliament and Council of the European Union 24 May 2014, here: Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC Text with EEA relevance)
- Ethics and data protection (European Commission 5 July 2021, here: Ethics and data protection)
- Guidelines 05/2020 on consent under Regulation 2016/679 (European Data Protection Board 4 May 2020, here: Guidelines 05/2020 on consent under Regulation 2016/679)
- Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (Text with EEA relevance, here: Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (Text with EEA relevance.))
- Assessment of the EU Member States' Rules on Health Data in the Light of GDPR (European Commission 2021, here: Assessment of the EU Member States' Rules on Health Data in the Light of GDPR)
- Handbook on European Data Protection Law (Publications Office of the European Union 2018, here: Handbook on European data protection law

Austria (for country-specific information see page 43)

- Digital Health Laws and Regulations 2021 (Global Legal Group 2021, here: Austria: Digital Health Laws and Regulations 2021)

Belgium (for country-specific information see page 47)

- Digital Health Laws and Regulations 2021 (Global Legal Group 2021, here: Belgium: Digital Health Laws and Regulations 2021)

Cyprus (for country-specific information see page 49)

Hungary (for country-specific information see page 51)

Italy (for country-specific information see page 54)

- Digital Health Laws and Regulations 2021 (Global Legal Group 2021, here: Italy: Digital Health Laws and Regulations 2021)

Luxembourg (for country-specific information see page 57)

Netherlands (for country-specific information see page 61)

Norway (for country-specific information see page 64)

- Data Protection Laws and Regulations 2021 (Global Legal Group 2021, here: Norway: Data Protections Laws and Regulations 2021)
- Guidelines by The Norwegian National Research Ethics Committee for Medical and Health Research (NEM) (Norwegian National Research Ethics Committee for medical and health research 2019, here: Guidelines by The Norwegian National Research Ethics Committee for medical and health research (NEM))

Poland (for country-specific information see page 67)

Portugal (for country-specific information see page 70)

Romania (for country-specific information see page 72)

Slovenia (for country-specific information see page 76)

- Data Protection Laws and Regulations 2021 (Global Legal Group 2021, here: Slovenia: Data Protections Laws and Regulations 2021)

Spain (for country-specific information see page 79)

- Digital Health Laws and Regulations 2021 (Global Legal Group 2021, here: Spain: Digital Health Laws and Regulations 2021)

Switzerland (for country-specific information see page 81)

- Digital Health Laws and Regulations 2021 (Global Legal Group 2021, here: Switzerland: Digital Health Laws and Regulations 2021)

State of Health

Definition:
In addition to the subjective state of health (based on Erhart et al. 2006:321ff), characterized by an independent assessment of one's own health, health should also be surveyed. For example, it can be determined via vital parameters (e.g. pulse, blood pressure, body temperature, respiration, etc.); clinical parameters (e.g. pulmonary function capacity, etc.); laboratory parameters (e.g. sodium, potassium, blood count, etc.); the number of risk factors; degrees of disability and restriction or diagnosed diseases.

Source of data:
Users and/or electronic health records (EHRs)

Concerning AAL solutions, the project team can partly collect objective health data directly from the users. The various devices provide vital and laboratory parameters. The users can also give insight into anonymized medical history via electronic health records (EHRs).

Object of measurement:
For measuring the objective state of health, for example, vital parameters, laboratory parameters, diagnosed diseases, and risk factors from the user's medical history and automated recording can be used. At least two measurements are necessary to establish comparisons. The following table gives an overview of potential measurement parameters and the distinction between the subjective and objective state of health

Table 32: Subjective and objective state of health

Subjective state of health	e.g., own assessment of my health today
Objective state of health	Vital parameters (e.g., pulse, blood pressure, body temperature, respiration, etc.)
Objective state of health	Clinical parameters (e.g., oxygen saturation, pulmonary function capacity, etc.)
Objective state of health	Laboratory parameters (e.g., sodium or potassium concentration, blood count, etc.)
Objective state of health	Number and type of risk factors (e.g., smoking, alcohol, exercise) Degree of disability and restriction (e.g. level of care allowance)
Objective state of health	Diagnosed (pre-existing) diseases

Source: own representation

For the application area of care, blood pressure, body temperature, blood sugar, BMI (Body Mass Index) and pulse can be measured directly by nurses. In the intramural setting, a blood count can be taken and laboratory parameters such as sodium and potassium can also be recorded.

Time of measurement:
In order to be able to compare the measurement results, several measurement dates are appropriate. Measurement should be arranged before the introduction of the AAL solution in order to be able to present potential changes after the introduction of the technology. Ideally, an intervention and control group are formed and continuous measurements are performed over the entire course of the project.

Measurement mode:
Measurement is made by manual reading of the devices or the documentation or by automatic evaluations of the laboratory devices. Medical professionals should be consulted for the interpretation of data.

Further notes:
Previously, there were discussions with experts and within the research team as to whether the indicators subjective health status and objective health status are comparable and which indicator is best suited for describing the state of health and should therefore be included in the indicator set.

In a large study (n=16,074) in China, Wu et al. (2013) were able to prove that the subjective state of health is consistent with the objective state of health and can be used as a general benchmark for the common population. Even among people over 60 years of age, the subjective state of health is comparable to the objective state of health according to a Chinese study (n=1,096) by Meng et al. (2014).

Nevertheless, the project team suggests collecting relevant data on the state of health subjectively and objectively for the respective AAL solution if possible. In the AAL setting, invasive measurements should be avoided. These are exclusively located in clinical settings.

Databases and cross-references to country-specific information:

European Union

- Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (Text with EEA relevance, here: Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (Text with EEA relevance)
- Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC Text with EEA relevance (European Parliament and Council of the European Union 24 May 2014, here: Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC Text with EEA relevance)
- Ethics and data protection (European Commission 5 July 2021, here: Ethics and data protection)
- Guidelines 05/2020 on consent under Regulation 2016/679 (European Data Protection Board 4 May 2020, here: Guidelines 05/2020 on consent under Regulation 2016/679)
- Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (Text with EEA relevance, here Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (Text with EEA relevance.))
- Assessment of the EU Member States' Rules on Health Data in the Light of GDPR (European Commission 2021, here Assessment of the EU Member States' Rules on Health Data in the Light of GDPR)
- Handbook on European Data Protection Law (Publications Office of the European Union 2018, here Handbook on European data protection law

Austria (for country-specific information see page 43)

- Electronic health records, i.e., Elektronische Gesundheitsakte (see here: ELGA)
- Digital Health Laws and Regulations 2021 (Global Legal Group 2021, here: Austria: Digital Health Laws and Regulations 2021)

Belgium (for country-specific information see page 47)

- Electronic health records, i.e., Summarized Electronic Health Record (see here: SUMHER)
- Digital Health Laws and Regulations 2021 (Global Legal Group 2021, here: Belgium: Digital Health Laws and Regulations 2021)

Cyprus (for country-specific information see page 49)

Hungary (for country-specific information see page 51)

- Electronic health records, i.e., Elektronikus Egészségügyi Szolgáltatási Tér (see here: EESZT)

Italy (for country-specific information see page 54)

- Electronic health records, i.e., Fascicolo Sanitario Elettronico (see here: Fascicolo Sanitario Elettronico)
- Digital Health Laws and Regulations 2021 (Global Legal Group 2021, here: Italy: Digital Health Laws and Regulations 2021)

Luxembourg (for country-specific information see page 57)

- Electronic health records, i.e., Dossier de soins partagé (see here: DSP)

Netherlands (for country-specific information see page 61)

- Electronic health records, i.e., Persoonlijke gezondheidsomgeving (see here PGO)

Norway (for country-specific information see page 64)

- Electronic health records, i.e., Digital Health Services (see here: HELSENORGE)
- Data Protection Laws and Regulations 2021 (Global Legal Group 2021, here: Norway: Data Protections Laws and Regulations 2021)
- Guidelines by The Norwegian National Research Ethics Committee for Medical and Health Research (NEM) (Norwegian National Research Ethics Committee for medical and health research 2019, here: Guidelines by The Norwegian National Research Ethics Committee for medical and health research (NEM))

Poland (for country-specific information see page 67)

- Electronic health services and records, i.e. E-usługi (see here: E-usługi)

Portugal (for country-specific information see page 70)

- Electronic health records, i.e., ePortugal (see here: ePortugal)

Romania (for country-specific information see page 72)

- lectronic health records, i.e., Dosarul Electronic de Sănătate (see here: DES)

Slovenia (for country-specific information see page 76)

- Electronic health records, i.e., zVEM (see here: zVEM)
- Data Protection Laws and Regulations 2021 (Global Legal Group 2021, here: Slovenia: Data Protections Laws and Regulations 2021)

Spain (for country-specific information see page 79)

- Electronic health records, i.e., É-Saúde (see here: É-Saúde)
- Digital Health Laws and Regulations 2021 (Global Legal Group 2021, here: Spain: Digital Health Laws and Regulations 2021)

Switzerland (for country-specific information see page 81)

- Electronic health records, i.e., Elektronisches Patientendossier (see here: EPD)
- Digital Health Laws and Regulations 2021 (Global Legal Group 2021, here: Switzerland: Digital Health Laws and Regulations 2021)

Active/Passive Usage

Definition:
Active usage is when users consciously interact with a system (voluntary and controlled input or output). Passive usage is defined as when the system is active but the users do not consciously interact with it.

Source of data:
Users or software

The respective developed software serves as the data source. Within the framework of the development of the AAL solution, care must be taken to ensure that this solution's active and passive usage can be recorded by the software.

Object of measurement:
During project planning, the research team must determine what is understood as active usage or passive usage in the concrete case of application. Active usage is, for example, when users actively use the tablet to chat, play games or look at their health data. An example of passive usage is the pedometer, which is integrated into the smartwatch and runs in the background.

Time of measurement:
Data on usage should be collected continuously so that changes over time can be accurately represented. If possible, researchers should collect data over the entire project period.

Measurement mode:
How data can be retrieved depends on the respective project structure and software. Usually, the recorded activity data are stored in databases, which can then be readout.

Further notes:
Data on active/passive usage allows concluding the usage behavior of participants. Davis et al. (1989) have shown with the technology acceptance model that using technology is centrally dependent on two variables: perceived usefulness and perceived ease-of-use. The usage behavior subsequently influences whether and which effects the technical system has on everyday life and the subjective quality of life of the target group (Kada et al. 2017:23).

Databases and cross-references to country-specific information:

European Union

- Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (Text with EEA relevance, here: Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (Text with EEA relevance)
- Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC Text with EEA relevance (European Parliament and Council of the European Union 24 May 2014, here: Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC Text with EEA relevance)
- Ethics and data protection (European Commission 5 July 2021, here: Ethics and data protection)
- Guidelines 05/2020 on consent under Regulation 2016/679 (European Data Protection Board 4 May 2020, here: Guidelines 05/2020 on consent under Regulation 2016/679)
- Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (Text with EEA relevance, here: Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (Text with EEA relevance.))
- Assessment of the EU Member States' Rules on Health Data in the Light of GDPR (European Commission 2021, here: Assessment of the EU Member States' Rules on Health Data in the Light of GDPR)
- Handbook on European Data Protection Law (Publications Office of the European Union 2018, here: Handbook on European data protection law

Austria (for country-specific information see page 43)

- Digital Health Laws and Regulations 2021 (Global Legal Group 2021, here: Austria: Digital Health Laws and Regulations 2021)

Belgium (for country-specific information see page 47)

- Digital Health Laws and Regulations 2021 (Global Legal Group 2021, here: Belgium: Digital Health Laws and Regulations 2021)

Cyprus (for country-specific information see page 49)

Hungary (for country-specific information see page 51)

Italy (for country-specific information see page 54)

- Digital Health Laws and Regulations 2021 (Global Legal Group 2021, here: Italy: Digital Health Laws and Regulations 2021)

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- Data Protection Laws and Regulations 2021 (Global Legal Group 2021, here: Norway: Data Protections Laws and Regulations 2021)
- Guidelines by The Norwegian National Research Ethics Committee for Medical and Health Research (NEM) (Norwegian National Research Ethics Committee for medical and health research 2019, here: Guidelines by The Norwegian National Research Ethics Committee for medical and health research (NEM))

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- Digital Health Laws and Regulations 2021 (Global Legal Group 2021, here: Switzerland: Digital Health Laws and Regulations 2021)

Error Data

Definition:
Error data is divided up into two groups: subjective and objective errors. A subjective error occurs in the case of an unsuccessful attempt to perform a task, regardless of where the cause is subjectively located (software, hardware, user). An objective error or unexpected system status occurs when an intended function cannot be carried out. Such an error can be software-related or hardware-related.

Source of data:
Logfile of the developed software/survey among users in a laboratory setting through usability test/evaluation of helpdesk data

In the first step, the research team has to identify the unexpected behavior (the error) in the log file or database or observe it in a laboratory setting. In the next step, researchers can evaluate the data/observations and subsequently analyze this information.

Object of measurement:
The number and extent of subjective and objective errors are measured. What exactly constitutes an error must be determined individually by the research team for each project. The errors can be divided into subjective errors triggered by the user, e.g. by clicking incorrectly in the software, incorrect configuration of wearables, etc., and objective errors, e.g. no GPS reception on the smartwatch. Furthermore, the project team can categorize the different errors, e.g. severity of the error, system aspects affected, reproducibility, error triggered by software, hardware, or user.

Time of measurement:
Typically, error data are recorded continuously and changes can be accurately represented over a period of time. If possible, researchers should collect, evaluate and analyze the entire measurement period.

Measurement mode:
How data are measured must be adapted individually. The techniques of data validation (checking the entered or recorded data for completeness and usefulness) & pattern recognition (automatic recognition of patterns, regularities, repetitions, or laws) can support this process (ÖNORM 2011:5ff).

In the case of subjective error data, e.g. collected through the number of calls to the helpdesk, these can be analyzed according to the type, extent, and duration of the error. The procedure could look like this, for example: First, a process is defined. Afterward, an initial check takes place in the laboratory setting to see whether the test persons adhere to the process as planned (similarity to users is important). Parallel to this, an evaluation is carried out by experts, and any errors are corrected. Finally, the product/service can be rolled out. Also during the

field test, there should be a constant evaluation of possible errors and potential corrections of these.

Further notes:
Here, reference can be made to EN ISO 9241-110 (2006:4-8f), in which the seven dialogue principles for interactive systems are defined. One such principle is fault tolerance. In this context, Hofmann (2008) points out that a system that acts interactively must demonstrate fault tolerance to its user. “This means that, on the one hand, it prevents the user from making mistakes - for example, by means of clearly understandable security questions, but on the other hand, it constructively supports the user in the event of an error so that the error can be rectified without too much effort.

Within the framework of the evaluation of the indicator, it is therefore also relevant to constructively discuss the causes of the errors that have occurred as well as improvement potentials. Accordingly, updates of the software or the like to improve the usability of the system are also to be treated as data discontinuity in the measurement period.

A potential parallel reactive questioning of the users about the errors that occurred can broaden understanding of the AAL solution and better explain user behavior. The results about the errors that occurred and their correction should be incorporated in training and documentation.

The ISO 9241-210 2010 standard provides many checklists that can support the process of designing usable interactive systems. These checklists include, for example, items on principles of human-centered design, planning of human-centered design, and human-centered design activities.

Databases and cross-references to country-specific information:

European Union

- Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (Text with EEA relevance, here: Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (Text with EEA relevance)
- Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC Text with EEA relevance (European Parliament and Council of the European Union 24 May 2014, here: Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC Text with EEA relevance)
- Ethics and data protection (European Commission 5 July 2021, here: Ethics and data protection)
- Guidelines 05/2020 on consent under Regulation 2016/679 (European Data Protection Board 4 May 2020, here: Guidelines 05/2020 on consent under Regulation 2016/679)
- Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (Text with EEA relevance, here: Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (Text with EEA relevance.))
- Assessment of the EU Member States' Rules on Health Data in the Light of GDPR (European Commission 2021, here: Assessment of the EU Member States' Rules on Health Data in the Light of GDPR)
- Handbook on European Data Protection Law (Publications Office of the European Union 2018, here: Handbook on European data protection law

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Human Assistance Costs

Definition:
Human assistance costs are defined as consumption of raw materials, auxiliary and operating materials, externally sourced primary products (material costs), and personnel costs for human assistance in the usage of AAL products and components. This includes, among other things, user training as well as support and service activities.

Source of data:
Providers of the AAL product or service and secondary data and/or official statistic authorities

The costs or price of an AAL product or service includes all costs and follow-up costs incurred by the user from the usage of an AAL product or service (based on Scharf, Schubert & Hehn 2015:337). This includes user training and support as well as service information. This measuring guide focuses on the immediate costs that arise from the use of an AAL solution. Medium- to long-term costs are discussed in more detail in the measuring guide for operating materials and maintenance costs.

If the provider of the AAL product or service does not provide the relevant information, secondary data from official statistics can be used for approximating the data needed. The data is broken down by industry (Statistical classification of economic activities in the European Community; i.e., NACE) and/or by occupation (International Standard Classification of Occupations; i.e.; ISCO) in the respective countries. In the case of international comparative analyses, it is essential to take the respective national purchasing power standard (PPS) into account in the analysis.

Object of measurement:
Human assistance costs are direct costs that can arise when using the AAL product or the AAL service, e.g. training of users, service information at helpdesks, or support services. The research project IntegrAAL distinguishes three categories of assistance costs depending on the necessary qualification of the respondents (based on Kumpf et al. 2014:93f):

- Level A: Assistance work can be performed by any person
- Level B: Assistance work does not require specific qualification, but good physical general condition
- Level C: Assistance work requires specific professional qualifications, e.g. doctors, certified caregivers, computer technicians

A potentially helpful categorization of assistance costs is to be determined by the project team for the specific AAL application. Costs for human assistance are not only characterized by personnel costs. For example, when a qualified nurse carries out diabetes training, he/she will need blood glucose meters, blood glucose test strips, training material, etc.

Time of measurement:
Costs for human assistance of the application of the AAL products and services should be recorded on the one hand for specific time intervals (e.g. month of commissioning) and on the other hand for the total duration of the project (based on OECD, 2018:152).

Measurement mode:
Data should be requested from the AAL product or service providers, as they are most qualified to provide information on the respective costs or can draw on empirical values. Data can be collected in different ways, e.g. with a paper or online questionnaire, by telephone, or through personal interviews (based on OECD 2018:218).

Databases and cross-references to country-specific information:

European Union and EFTA

- Database - Labour Market (incl. LFS). (n.d.). Eurostat (see here: Earnings)
- Database - Purchasing power parities. (n.d.). Eurostat (see here: Purchasing power parities)

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Financial Burden for Users

Definition:
Periodized expenditure valued in the form of money by a primary, secondary or tertiary user in a periodized accounting period for the usage of AAL products and components.

Source of data:
Providers of the AAL solution/developers as well as users and secondary data and/or official statistic authorities

The research team collects data from the AAL product or service providers or from the *primary*, *secondary* or *tertiary* users. Primary users are people who benefit directly from AAL, secondary indirect users such as formal and informal health and care service providers, and tertiary users are those who do not use AAL directly but are involved in its organization and financing in some way or other (e.g. political decision-makers, representatives of social and/or private insurance companies).

In international comparative analyses, it is essential to consider the respective national purchasing power standard (PPS) as well as the corresponding Classification of Individual Consumption by Purpose (COICOP) in the analysis.

Object of measurement:
The total financial burden for primary, secondary or tertiary users includes investment and de-investment costs (see **investment, installation and de-installation costs**; e.g. **acquisition costs of the AAL product, installation costs, training costs, and de-installation costs**) as well as costs for ongoing operation and maintenance (see **operating materials and maintenance costs**; e.g. **electricity costs, insurance, repairs or technical operating costs**). Furthermore, additional service costs can arise that are attributable to the AAL product or service. The following table contains a comprehensive presentation of cost positions that should be recorded.

Table 33: Burden categories

Investment costs (and de-investment costs):
Acquisition costs
Installation costs
Training for (end) users and others
De-installation costs (e.g. after project completion, after death, after a change of care type)
Costs of ongoing operation/maintenance:
Technical operating costs
Repairs
Insurances
Electricity costs
Emergency services etc.
Additional service costs (attributable to AAL product)

Source: Kumpf et al. 2014:92ff; own representation

Time of measurement:
Costs should be reported for the entire period when the user uses the AAL product or service. This approach is supposed to ensure an exact allocation of costs; regardless of the actual outgoing payment (based on OECD 2018:152).

Measurement mode:
Data should be requested from the AAL product or the AAL service providers, as they are most qualified to provide information on the respective costs or can draw on empirical values. However, certain parameters, such as electricity consumption, possibly need to be requested directly from the users. Data can be collected in various ways, e.g. by paper or online questionnaires, telephone, or personal interviews (based on OECD 2018:218).

Further notes:
“Prior to the start of the project, it has to be clarified which form of cost allocation and recording will actually be carried out. AAL projects are usually characterized by specific cost units (funding agencies, non-profit, and other project partners), i.e. in some cases market prices are not charged in projects or market prices are not yet available, which could partly impede a realistic cost calculation.” (based on Kumpf et al. 2014:93ff). If market prices are already available, they should be used to ensure a realistic representation of the financial burden for end users.

Databases and cross-references to country-specific information:

European Union and EFTA

- Database - Labour Market (incl. LFS). (n.d.). Eurostat (see here: Earnings)
- Database - Purchasing power parities. (n.d.). Eurostat (see here: Purchasing power parities)

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Costs and Revenues during Development and Market Launch

Definition:
Costs are defined as the usage or consumption of production factors valued in the form of money (e.g. quantity of input factors or time), which arise within a certain period of time (e.g. months or years).
Revenues denote the performance-related creation of goods and services, valued in the form of money, as well as their utilization within a specific accounting period (based on Hoitsch & Lingnau 2007:16; von Känel 2008:22).

Source of data:
R&D performing institution/company/product developers and secondary data and/or official statistic authorities

On the one hand, the primary focus of companies is on cost minimization, i.e. the prime costs in the development and production of AAL solutions/components should be as low as possible, and, on the other hand, it is on revenue maximization, so that company profits are developed to the maximum.

The measurement of costs and revenues should take place at the institution/company/product developers carrying out R&D since they bear the responsibility for the costs and are obliged to document these due to applicable legal regulations (based on Ehrlenspiel et al. 2005:5).

If the developer of the AAL product or service does not provide the relevant information, secondary data from official statistics can be used for approximating the data needed. The data is broken down by industry (Statistical classification of economic activities in the European Community; i.e., NACE) and/or by occupation (International Standard Classification of Occupations; i.e.; ISCO) in the respective countries. In international comparative analyses, it is essential to consider the respective national purchasing power standard (PPS) as well as the corresponding Classification of Individual Consumption by Purpose (COICOP) in the analysis.

Object of measurement:
The categories listed in the following table are to be used to determine the **costs** involved in the development and market launch of AAL solutions/components.

Table 34: Categories of R&D expenses

Sum of R&D expenses
Capital expenditure
Land and buildings
Machinery and equipment
Activated computer software
Other products of intellectual property
Current expenses
Personnel expenses
Other current expenses
Operating materials and maintenance costs

Source: Based on OECD (2018:142); own representation

R&D capital expenditure is the gross annual amount paid for the acquisition of assets for the performance of research and development that are used repeatedly or continuously for more than one year. R&D capital expenditures include tangible assets (physical assets such as buildings and facilities or machinery and equipment) and intangible assets (e.g. computer software and other intellectual property products).

Current R&D expenses are composed of R&D-related personnel and other current expenses. Services and goods (including equipment) consumed within one year are included in current expenses. Annual fees or rents for the use of assets should also be considered in current expenses (based on OECD 2018:129).

Personnel expenses include remuneration for employed, non-independent R&D staff, such as annual wages and salaries and any related costs or fringe benefits (e.g. bonus payments, stock options, and holiday pay, in addition to pension and other social security contributions, payroll taxes, and duties, etc.). It is important to consider personnel expenses for employees only to the extent to which they contribute directly to research and development (based on OECD 2018:130).

Other current R&D expenses are defined as purchases and rentals of materials, commodity goods, equipment, and services from private or public institutions that do not fall in the category of investments within a reference year (e.g. water, gas, electricity, specialist books, journals, royalties and license fees for the use of patents and other intellectual property rights, or leasing of capital goods; based on OECD 2018:132). Administrative and overhead costs (e.g. office space, IT and telecommunications, building maintenance, insurance) should also be included in other current expenses and prorated if necessary (based on OECD 2018:133).

The sums of R&D expenditures of a project or product development should be recorded and reported at purchase prices. Purchase prices are prices paid by research institutions and companies without taking into account deductible percentages of VAT and similar taxes. These reflect the actual costs incurred during the research and development of AAL solutions (based on OECD 2018:136).

With regard to **revenues**, it can be assumed that R&D performing institutions and facilities such as companies, universities, and universities of applied sciences are financed by third-party funds from national or international research funding, by contract research from public and private economy, or by subsidies and financial aid. In some cases, R&D is financed at least partially or exclusively with internal means (equity capital) (based on OECD 2018:149f).

The (imputed) profit or loss for the project duration is calculated from the difference between the revenues related to the time period and the costs to be compared with them (based on von Känel 2008:197).

Time of measurement:
Costs and revenues should be reported for the period in which R&D is conducted and not for the period in which own or third-party funds have been received (based on OECD 2018:152). This is to ensure an exact allocation of costs and revenues to the respective R&D process, regardless of the actual incoming or outgoing payments.

Measurement mode:
Data can be collected in different ways, e.g. with a paper or online questionnaire, by telephone, or through personal interviews. If accessible, data could also be obtained from administrative sources of the public sector (based on OECD 2018:218). Personal coordination with the institution conducting R&D is recommended in any case to avoid misunderstandings.

Further notes:
It must be clarified before and during the course of the project which of the cost parameters presented above are to be recorded. Development costs are particularly difficult to determine, as they are often based on already existing projects. For this reason, only the research and development costs attributable to the project should be recorded if possible.

Databases and cross-references to country-specific information:

European Union and EFTA

- Database - Labour Market (incl. LFS). (n.d.). Eurostat (see here: Earnings)
- Database - Purchasing power parities. (n.d.). Eurostat (see here: Purchasing power parities)

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Operating Materials and Maintenance Costs

Definition:
The consumption of raw materials, auxiliary and operating materials, externally sourced primary products (material costs) as well as personnel costs for the operation and maintenance of AAL products and components valued in monetary terms (based on von Känel 2008:150).

Source of data:
Providers of the AAL product and/or AAL service and secondary data and/or official statistic authorities

The cost or price of an AAL product or service includes all costs and follow-up costs incurred by primary, secondary, or tertiary users from the usage of an AAL product or service (based on Scharf et al. 2015:337). This measurement guide focuses on running costs that arise from the usage of an AAL solution. These particularly include **running costs** for **operating materials and maintenance costs**. **One-off costs** such as **investment, installation, and de-installation costs** or **human assistance costs** are discussed in more detail in another measurement guide.

If the provider of the AAL product or service does not provide the relevant information, secondary data from official statistics can be used for approximating the data needed. The data is broken down by industry (Statistical classification of economic activities in the European Community; i.e., NACE) and/or by occupation (International Standard Classification of Occupations; i.e.; ISCO) in the respective countries. In international comparative analyses, it is essential to consider the respective national purchasing power standard (PPS) as well as the corresponding Classification of Individual Consumption by Purpose (COICOP) in the analysis.

Object of measurement:
Operating materials and maintenance costs are a sub-category of the category “other current expenses” of the indicator “costs and revenues during development and market launch”.

Running costs of operation and maintenance of AAL products and services (e.g. technical operating costs, repairs, insurance, emergency services for a telemonitoring system) should be recorded and reported at purchase prices. Purchase prices are the prices paid by primary, secondary, and tertiary users without taking into account the deductible percentage of VAT and similar taxes. Purchase prices reflect the actual costs incurred by users (based on OECD 2018:136; Kumpf et al. 2014:93).

Any personnel costs that are research-related and associated with the ongoing operation and maintenance of an AAL solution are also to be included in this regard. These costs should be differentiated from personnel costs that are one-off costs, incurring e.g. during the installation or de-installation of an AAL product or service (see **investment, installation, and de-installation costs**).

Time of measurement:
The costs for operation and maintenance should be recorded for specific time intervals (e.g. month of commissioning) as well as for the total duration (based on OECD 2018:152).

Measurement mode:
Data should be requested from the AAL product or service providers, as they are most qualified to provide information on the respective prices or can draw on empirical values. Data can be collected in various ways, e.g. by paper or online questionnaires, telephone, or personal interviews (based on OECD 2018:218).

Further notes:
It must be clarified before and during the course of the project which operating materials and maintenance costs are to be recorded. Particularly in the case of operating materials, there is a possibility that these will be allocated to overhead costs since they are not clearly attributable. Therefore, care should be taken to avoid double counting and/or double billing.

Databases and cross-references to country-specific information:

European Union and EFTA

- Database - Labour Market (incl. LFS). (n.d.). Eurostat (see here: Earnings)
- Database - Purchasing power parities. (n.d.). Eurostat (see here: Purchasing power parities)

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Investment, Installation, and De-installation Costs

Definition:
Investment and installation costs are defined as expenses for fixed assets such as machines, buildings but also initial equipment, spare parts, computer systems, etc. as well as associated installation costs (e.g. transport, assembly), which are usually one-off costs. De-installation costs are incurred after the service life when long-term assets are no longer needed (e.g. dismantling, removal, disposal).

Source of data:
R&D performing institution/company/product developers and secondary data and/or official statistic authorities

The cost or price of an AAL product or service includes all costs and follow-up costs incurred by the primary, secondary or tertiary user from the usage of an AAL product or service (based on Scharf et al. 2015:337). This measurement guide focuses on investment, installation, and de-installation costs.

In international comparative analyses, it is essential to consider the respective national purchasing power standard (PPS) as well as the corresponding Classification of Individual Consumption by Purpose (COICOP) in the analysis.

Object of measurement:
Investment, installation, and de-installation costs are a sub-category of capital expenditure or the machinery and equipment of the indicator (see **costs and revenues during development and market launch**).

It is necessary to record any costs for the delivery, assembly, installation, and de-installation (e.g. after the end of a project test phase or the decease of primary end-users) and to assess them at the purchase prices (excluding VAT, etc. where applicable) of primary, secondary or tertiary users monetarily (based on Kumpf et al. 2014:93).

Personnel costs associated with the installation and de-installation of AAL solutions are usually one-off costs and must be assigned to this category. Not included are personnel expenses that are attributed to current expenses (see **current expenses** in **costs and revenues during development and market launch).**

Time of measurement:
Investment, installation, and de-installation costs should be reported for the period in which they are incurred.

Measurement mode:
Data should be requested from providers of the AAL product or the AAL service, as they are most qualified to provide information about the respective costs. Data collection can take place in different ways, e.g. with a paper or online questionnaire, by telephone, or through personal interviews.

Databases and cross-references to country-specific information:

European Union and EFTA

- Database - Labour Market (incl. LFS). (n.d.). Eurostat (see here: Earnings)
- Database - Purchasing power parities. (n.d.). Eurostat (see here: Purchasing power parities)

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Market Potential

Definition:
Market potential is understood as the capacity of a market and the total possible sales volume of a market for a certain product or service. Market potential forms the upper limit for market volume.

Source of data:
Secondary data and secondary data and/or official statistic authorities

On the one hand, AAL technologies are characterized by push factors, in particular by technological progress and the associated development of new products and services. On the other hand, there are pull factors, above all the steady increase in the number of older people, which characterize this market (based on AAL Association 2014:8).

Due to these determinants, there is a very wide range of application areas and thus possible AAL solutions that attempt to increase or at least maintain the quality of life of older people. This results in a very indeterminate market term for AAL instead of a specific term, which can vary depending on the respective area of application of the solution and the therefore heterogeneous users, who differ e.g. in their health deficits. In particular, users influence the potential sales volume of an AAL solution, which needs to be defined in more detail in the next step.

Object of measurement:
Apart from the quantity sold, the possible number of consumers of AAL products and service solutions is one of the basic parameters for determining the market potential.

Consumers are further subdivided into primary users, i.e. people who benefit directly from AAL, secondary users, i.e. indirect users such as formal and informal health and care service providers, and tertiary users who do not use AAL directly but are involved in some way in its organization and financing (e.g. political decision-makers, representatives of social and/or private insurance companies). In the following, some measured quantities are presented that are either directly or indirectly relevant for determining the market potential.

Table 35: Measured quantities for determining market potential

Development of the AAL market
Current and potential users: Data on current and potential users (demographic data, user segments/profiles); socio-demographic indicators; socio-economic indicators; internet usage; technology orientation
Market value and size: intensity of usage; distribution rate; income and expenses; main benefits/problems
Market developments and driving forces: information on technology trends; emerging solutions (future products, forecasts, strategy plans, etc.); user perception; expectations; satisfaction
Interoperability and standardization issues: information on adopted/current standards
Development of key players
Number and type of key players and new market entrants: total; by market segment; by classification; by company size; business and marketing measures; sustainable business models; time to market
Development of investments
Number and type of market offensives: start-up companies; mergers and acquisitions; IPOs; support programs; survival rate of start-ups; investments by market segment/type of solution

Source: Based on AAL Association (2014:28); own representation

In addition to the number of potential users, the sales volume of an AAL solution depends primarily on the purchasing power of private and/or public households that pay for the financing of the solution.
In contrast to market potential, the market volume describes the units actually sold (sales) or the corresponding monetary measured values (turnover).

Time of measurement:
Market potential should be calculated for a full calendar year or at least for a precisely defined period of time (e.g. the next 5 years). In addition, the geographical coverage area (e.g. country, federal state) should be defined. This ensures comparability from both a temporal and a geographical perspective and makes the analysis of past and future trends possible.

Measurement mode:
Depending on the indicator chosen, different types of data, i.e. quantitative data, market research data, and qualitative data can be used to determine the respective indicator.

Official statistics and resulting quantitative data are usually of high quality and reliability. Often these are collected transnationally - especially in the European Union (EU) - according to uniform standards so that comparability between the countries is given. These data are particularly suitable for determining demographic trends, health expenditure as a percentage of the gross domestic product, etc. However, they are often not suitable for the analysis of innovative

markets, products, and product segments, which means that the characteristics of a market can only be inadequately represented.
To analyze these, quantitative market research data should therefore be used, but these are often only available to a limited extent and, above all, only against payment. With regard to the survey methods and associated data, it must also be noted that not the same quality criteria apply as, for example, to the national statistical offices.

Compared to quantitative surveys, qualitative surveys such as guided expert interviews, focus group interviews, case studies, etc. are often less structured, which is at the expense of the comparability of results. However, they offer solid and in-depth market information when a specific segment of customers, stakeholders, market scenarios (e.g. depending on socio-demographic characteristics), etc. is to be analyzed.

Databases and cross-references to country-specific information:

European Union and EFTA

- Database - Population and demography. (n.d.). Eurostat (see here: Population and demography)
- Database - Population projections. (n.d.). Eurostat (see here: Population projections)
- Database - Labour Market (incl. LFS). (n.d.). Eurostat (see here: Earnings)
- Database - Digital economy and society. (n.d.). Eurostat. (see here: Digital economy and society)
- Database – Structural business statistics. (n.d.). Eurostat. (see here: Structural business statistics)
- Database – Science and technology. (n.d.). Eurostat. (see here: Science, technology and innovation)

Austria (for country-specific information see page 42)

Belgium (for country-specific information see page 45)

Cyprus (for country-specific information see page 48)

Hungary (for country-specific information see page 50)

Italy (for country-specific information see page 53)

Luxembourg (for country-specific information see page 56)

Netherlands (for country-specific information see page 59)

Norway (for country-specific information see page 62)

Poland (for country-specific information see page 65)

Portugal (for country-specific information see page 68)

Romania (for country-specific information see page 71)

Slovenia (for country-specific information see page 74)

Spain (for country-specific information see page 77)

Switzerland (for country-specific information see page 80)

Avoided Resource Requirements

Avoided resource requirements are defined as cost reduction valued in the form of money

Source of data:
Secondary data and/or official statistic authorities and/or electronic health records (EHRs)

This indicator focuses on the use of formal and informal care and support services or the reduced use of these as a result of the use of AAL products and services and the (monetary) savings potentially associated with this. This applies, among others, to care and permanent care facilities, mobile caregivers and other health care professions (based on OECD, 2017:309-312).

Potential data sources are official statistics authorities (e.g., Eurostat), the Organisation for Economic Co-operation and Development (OECD), and the World Bank. The users can also provide an insight into the usage of health and care services via electronic health records (EHRs).

In the case of international comparative analyses, it is essential to take the respective national purchasing power standard (PPS) into account in the analysis.

Object of measurement:
Changes in the utilization of informal and formal care services can be expressed in natural units such as

- number of days of care, number of discharges (for permanent care facilities
- number of consultations and treatment cases (for mobile nurses/caregivers and other health professionals),
- time spent in hours (for informal caregivers and attendants).

The conversion of natural units into a monetary measured value is based on secondary data that quantify the respective average cost of a unit used.

Time of measurement:
The usage of formal and informal care and support services should be recorded, on the one hand, for specific time intervals (e.g. 4 weeks) and, on the other hand, at the beginning and end of an AAL project test phase (based on OECD 2018:152).

Measurement mode:
Data collection can take place through different modes, e.g. a paper or online questionnaire, by telephone, or even personal interviews (based on OECD 2018:218). Data should be requested from the respective formal and informal service providers or collected from the users. Data provision should be anonymized and, if possible, provided in aggregated form for both the intervention and a control group.

Databases and cross-references to country-specific information:

European Union and EFTA

- Database - Labour Market (incl. LFS). (n.d.). Eurostat (see here: Earnings)
- Database - Purchasing power parities. (n.d.). Eurostat (see here: Purchasing power parities)
- Database - Health. (n.d.). Eurostat (see here: Health)
- OECD Health Statistics 2021 - OECD. (n.d.). OECD (see here: OECD Health Statistics)
- Health Nutrition and Population Statistics | DataBank. (n.d.). World Bank (see here: Health Nutrition and Population Statistics)

Austria (for country-specific information see page 42)

- Electronic health records, i.e., Elektronische Gesundheitsakte (see here: ELGA)

Belgium (for country-specific information see page 45)

- Electronic health records, i.e., Summarized Electronic Health Record (see here: SUMHER)

Cyprus (for country-specific information see page 48)

Hungary (for country-specific information see page 50)

- Electronic health records, i.e., Elektronikus Egészségügyi Szolgáltatási Tér (see here: EESZT)

Italy (for country-specific information see page 53)

- Electronic health records, i.e., Fascicolo Sanitario Elettronico (see here: Fascicolo Sanitario Elettronico)

Luxembourg (for country-specific information see page 56)

- Electronic health records, i.e., Dossier de soins partagé (see here: DSP)

Netherlands (for country-specific information see page 59)

- Electronic health records, i.e. Persoonlijke gezondheidsomgeving (see here: PGO)

Norway (for country-specific information see page 62)

- Electronic health records, i.e., Digital Health Services (see here: HELSENORGE)

Poland (for country-specific information see page 65)

- Electronic health services and records, i.e. E-usługi (see here: E-usługi)

Portugal (for country-specific information see page 68)

- Electronic health records, i.e., ePortugal (see here: ePortugal)

Romania (for country-specific information see page 71)

- Electronic health records, i.e., Dosarul Electronic de Sănătate (see here: DES)

Slovenia (for country-specific information see page 74)

- Electronic health records, i.e., zVEM (see here: zVEM)

Spain (for country-specific information see page 77)

- Electronic health records, i.e., É-Saúde (see here: É-Saúde)

Switzerland (for country-specific information see page 80)

- Electronic health records, i.e., Elektronisches Patientendossier (see here: EPD)

3.3. Application Example Care & Support: 24h QuAALity – Quality Assurance in 24-Hour Care

Brief description of the AAL solution:[4] Due to demographic change, the need for 24-hour care is increasing in addition to the need for professional and institutional care. 24-hour care is a cornerstone of care of the elderly due to its cost efficiency and a large amount of time it takes to provide care. With over 60,000 users in Austria, it is an important alternative to family care and mobile care. The individuals receiving care range from elderly people who only need support with household-related activities to people with high care needs for round-the-clock care. Personal caregivers often commute between Austria and their respective home countries (mainly Slovakia, Hungary, and Romania) for the care work at a time interval of two or more weeks. Stressful working conditions arise mainly due to language problems, isolated living together with a person suffering from dementia, for example, in combination with little or no specialist training and quality control.
The aim of the project is to develop and evaluate a distributed software solution for the support and quality assurance of 24-hour care. This will be developed as a cross-platform application software by means of a systematic survey of the needs of caregivers, families concerned, particularly people cared for, placement agencies, and professional health and nursing staff. The application software contains:

1. information and further education portal (eLearning) with interactive learning elements on common clinical pictures and short videos on recurring care situations in German as well as in Slovakian, Hungarian, and Romanian as the most common languages of caregivers.
2. comprehensive electronic care documentation, which supports quality assurance and ensures transparency between those involved.
3. integrated emergency management that enables caregivers to respond quickly and professionally to occurring emergency situations.
4. links to translation sites or networking opportunities with (family) members and other tools for everyday care life.

The application software is intended to reach caregivers in a low-threshold way in order to improve the quality of care and thus the quality of life of those affected. Through the large-scale longitudinal evaluation design, involving more than 100 test households of 24-hour care for a period of twelve months, the effectiveness is recorded multidimensionally. The central result at the end of the project will be a market-oriented, validated software solution that supports a high-quality, secure and stable care situation. Particularly the individuals cared for but also their relatives and placement agencies, which are supported in achieving successful care arrangements, benefit from qualification measures of caregivers. This also corresponds to the goals of the current government program.

[4] Werner, F. (2019), 24h QuAALity – brief description; https://projekte.ffg.at/projekt/3076586

Project data:

Duration:	01 January 2019 – 31 December 2021
Funding authority:	Federal Ministry for Climate Action, Environment, Energy, Mobility, Innovation and Technology (BMK, formally known as BMVIT)
Program management:	Austrian Research Promotion Agency (FFG)
Program:	ICT of the future: benefit – Opportunity through demographic change
Project management:	FH-Prof.in Mag.a Dr.in Elisabeth Haslinger-Baumann Dipl.-Ing. Mag. Franz Werner
Project partners:	University of Applied Sciences Campus Vienna Forschungs- und Entwicklungs (R&D) GmbH (project management) Österreichischer Gesundheits- und Krankenpflegeverband (Austrian health and nursing association) Home-Care-Management ALEXANDER WINTER e.U. CARITAS Rundum zu Hause betreut (home care round the clock) ipb - Institut für Personenbetreuung (institute for personal care) SMART ASSETS Development GmbH Johanniter Österreich Ausbildung und Forschung gemeinnützige GmbH (Johanniter Austria training and research non-profit GmbH) NOUS Wissensmanagement GmbH (NOUS knowledge management GmbH)

The aim of the AAL project 24h QuAALity - Quality assurance in 24-hour care is the development and evaluation of a distributed client-server software solution for quality assurance in 24-hour care. For this reason, this AAL solution is assigned to products and services of the care & support sector. This area of the application focuses on individuals who require assistance to perform basic daily activities over a longer period of time due to their age, disability, illness, or impairment. It also includes people who provide such assistance, i.e. informal and formal caregivers. The non-reactive measuring instruments that are relevant for the evaluation are described below.

As shown in Table 36, it is assumed that the project has a lead time (project months 9 to 18) of 10 months for development and design before the field test (project months 22 to 33) and a follow-up time (project months 34 to 36) of three months for the evaluation and dissemination of the project. Depending on the respective indicator, the determination of the same takes place in the field test phase, the lead time, or the follow-up time, as shown in the table. The following paragraphs provide more detailed information on the specific indicator.

Within the framework of the implementation of 24h QuAALity, **investment, installation and de-installation costs** arise due to the implementation of the application, which are usually one-off costs incurred in the initial project phase. These include, for example, the programming of the application (investment; project months 9 to 18) and the installation in the participating

100 test households (set-up and training; project months 19 to 21). At the end of the field test, possible de-installation costs should be taken into account (e.g. dismantling and removal; from project months 34 to 36).

Human assistance costs (for training, support, and services of primary (informal caregivers) and secondary users (formal caregivers) as well as expenses for **operating materials and maintenance** (technical operating costs (e.g. electricity), maintenance services for software updates, etc.) represent running costs that need to be paid and recorded at regular or irregular intervals (project months 22 to 33).

All expenditures for tangible investments (software, operating materials (e.g. electricity), etc.) are recorded at the purchase prices of the respective point in time (invoice date) without taking into account the deductible percentage of VAT and similar taxes. Installation, de-installation, and maintenance are primarily personnel-intensive services, which is why the number of hours required per household and the hourly rate paid to employees (including any overhead costs) is documented by the executing institution (e.g. University of Applied Sciences Campus Vienna). Any personnel costs that contribute directly to the research and (further) development of the AAL solution to be evaluated must be distinguished from personnel expenses incurred. These personnel costs must be added separately to the personnel costs of ongoing R&D expenses, which could prove difficult in everyday project life. Alternatively, it should be considered to deduct personnel costs incurred for installation, maintenance, etc. from the total personnel costs and allocate the resulting difference to **personnel costs for research and development** (within the indicator “costs and revenues during development and market launch”). Personnel costs are recorded over the entire period of the project (project months 1 to 36).

In order to assess the potential impacts of the AAL solution on resource consumption, it is recommended to quantify the usage of informal and formal care services or to calculate the **avoided resource requirements**. In order to sufficiently test this hypothesis, the utilization of selected formal and informal care and support services is recorded in natural units (e.g. number of hours of utilized formal and informal care services) for certain time intervals (e.g. four weeks) at the beginning (project months 19 to 22) and at the end (project months 33 to 36) of the field test.

Documentation takes place in test households where the AAL solution is installed as well as in control households where no change has been made. Finally, the results of the groups are compared and checked for significant differences as well as, based on data (e.g. of official statistics), converted into monetary units or the lower resource consumption is estimated.

Table 36: Proposal for the temporal determination of the parameter collection in 24h QuAALity

Project month	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**		**21**	**22**	**23**	**24**	**25**	**26**	**27**	**28**	**29**	**30**	**31**	**32**	**33**	**34**	**35**	**36**
Evaluation phase:		**Lead time**																					**Field phase**												**Follow-up time**		
Investment costs									■	■	■	■	■	■	■	■	■	■																				
Installation costs																			■	■	■	■																
De-installation costs																																			■	■	■
Human assistance costs																							■	■	■	■	■	■	■	■	■	■	■	■			
Operating materials and maintenance costs																							■	■	■	■	■	■	■	■	■	■	■	■			
Personnel costs (costs and revenues during development & market launch)	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■
Avoided resource re-quirements																			■	■	■	■	■											■	■	■	■
Consideration of ethical guidelines	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■
State of health (reactive)																			■	■	■	■	■											■	■	■	■
State of health (non-re-active)																							■	■	■	■	■	■	■	■	■	■	■	■			
Active/passive usage																							■	■	■	■	■	■	■	■	■	■	■	■			
Error data									■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■			
Market potential																																■	■	■	■	■	■

Source: own representation

The **consideration of ethical guidelines** must already be taken into account when writing the project application and throughout the entire duration of the project. This includes, especially in the initial phase, obtaining a declaration of consent from the responsible ethics committee as well as the targeted information of the recruited participants. This includes information about project goals, potential benefits, field test duration, time schedule, planned qualitative and/or quantitative surveys, voluntary participation as well as possibilities of opting out of the project. Confirmation of the explicit information on the applicable framework conditions is made in writing by signing the informed consent before project testing in the households. This informed consent must be guaranteed and communicated throughout the entire duration of the project.
Active usage of the AAL components in 24h QuAALity is defined by the project team as when the participants (caregivers, family members, or persons cared for) actively use the system, e.g. electronic care documentation, e-learning system, or integrated emergency management. A passive usage of the AAL component is not planned in this project. The evaluation of these user data during the field test (project months 22 to 33) allows conclusions to be drawn about the usefulness and user-friendliness. The collection of usage data takes place automatically through logging.
The **health status** of the more than 100 test households should be determined immediately before the beginning of the installation (project month 13) and at the end of the field test (project month 30) by means of validated questionnaires (e.g. EvAALuation² questionnaire, EQ-5D, WHOQOL BREF). The electronic documentation offers the opportunity to collect data on the subjective state of health during the entire field test, which in turn allows conclusions to be drawn about the AAL solution (project months 22 to 33).
The project team tests the system functions with test persons in a laboratory setting and analyses (subjective and objective) **error data** before the roll-out (project months 1 to 12). After the installation of the AAL software, participants reach the helpdesk by telephone in case of problems and, if necessary, staff members are sent on-site to solve the problem. In this regard, it is recorded which errors occur how often during the field test and how much time the respective service visits take (project months 9 to 33).
The **financial burden for end users** depends on the implementation of the AAL solution. The research project allows an approximate calculation of the costs for primary/secondary/tertiary users in case of a market introduction. If possible, the end users' marginal willingness to pay shall be gathered in order to be able to draw conclusions about other indicators.
The **market potential** should be determined in the last year of the project (project months 32 to 36), because it can be assumed that the first results of the acceptance analyses of 24h QuAALity will be already available by then. Such analyses make it possible to revise the system if necessary, i.e. to reduce or expand it by certain functions in order to advance the market maturity, and the market volume can be estimated by linking the willingness to pay with socio-economic data (e.g. purchasing power).
For the other indicators, a reactive gathering by means of the **questionnaire for care & support** is proposed. It offers the possibility of also recording the perspectives of care recipients.

The questionnaire contains the following subscales:

- Subjectively relevant activity level
- Autonomy & self-determination
- Life & health satisfaction
- Age(ing)-related self-image
- Health-promoting behavior
- Social interaction
- Social participation
- Access & offer healthcare
- Affordability of healthcare
- Services used (health care system)
- Care and support needs
- Therapy adherence/-compliance
- Willingness to pay
- Subjective intention of use
- Pragmatic user experience
- Stigma-free design
- Hedonic user experience
- Freedom of choice regarding service access
- Privacy

The subscales are all considered relevant for the test persons. Since 24h QuAALity does not include a (quasi-) experimental design, i.e. no control group is planned, the proof of efficacy has to be provided by comparing the values before and after the introduction of the solution. In order to determine the initial values, the questionnaire should exclude technology-related items, i.e. the operationalizations freedom of choice regarding service access, subjective intention of use, user experience, stigma-free design, and privacy from the user's perspective. Subsequently, at least one survey should be made at the end of the field phase, using the entire questionnaire in order to determine the effects. Furthermore, we recommend conducting interim surveys (e.g. after one month, three months, six months) in order to be able to understand change processes.
Assuming that some of the study participants need support in answering the questions, the survey could be conducted orally within the framework of 24h QuAALity. In this case, an examiner in charge reads out the instructions as well as questions and answer options. In addition, it should be explained that the questions will now be read aloud.
For example, the oral formulation of AS1 of autonomy & self-determination could read as follows: "On a scale of one to five, where one means 'do not agree at all', two means 'rather disagree', three means 'neither', four means 'rather agree' and five means 'completely agree', how would you rate the following statements: In my life, I can make independent decisions? So as not to burden the participants with formulations that are too long, the verbalizations of the answer levels can be abbreviated as follows: "On a scale of one to five, where one means

‘do not agree at all’ and five means ‘completely agree’, how would you rate the following statements:” The open-ended question on services used (health care system) “Which services, e.g. doctor’s visit, prescriptions, inpatient or outpatient stay, have you used in the last few weeks?" can be supplemented by “[...] Please list them!”

4. Being Active

In the following, the measuring instruments developed to evaluate the effects of AAL solutions in the area of care are presented.
This implies technologies that aim to support people who want to pursue employment (gainful employment, honorary or voluntary activity) and who want to be supported by technology in doing so. The target population comprises the users of these solutions. The reactive and non-reactive measuring instruments are based on the gathering of indicators which are summarised below. In addition, it is pointed out whether the respective indicator is to be collected reactively or non-reactively as well as the definition of the indicator and the source(s) that were incorporated into the creation of the operational definition. By clicking on "reactive" or "non-reactive" you can switch directly to the operationalization.

Vitality and Quality of Life Goals

Maintaining, expanding, or improving skills and independent activities:

Subjectively relevant activity level (reactive): Self-performance of activities that contribute to the well-being and are experienced as meaningful. This applies in particular to activities that contribute to maintaining or improving health and life satisfaction (based on Orem 2001; Pratt & Ashforth 2003; Diener, Emmons, Larsen & Griffin 1985).

Cognitive and mental abilities (reactive): The person's self-perceived abilities that relate to perception, thinking, or cognition and serve to fulfill subjectively relevant activities (based on Kent 2006s; Kaminski & Neisser 1994; Zimbardo 1995; Tuomi et al. 1998).

Physical abilities (reactive): Self-perceived physical abilities to perform subjectively relevant activities (based on Kent 2006b; Martin 2015).

Maintaining or improving well-being:

Autonomy & self-determination (reactive): Autonomy is the self-determined making of decisions. The following is subsumed under perceived self-determination: knowing the subjective degree of freedom from (1) obstacles, (2) possibilities of action, (3) choosing possibilities of activity, (4) acting (carrying out activities), and (5) the freedom to create new possibilities of activity for oneself. Self-assessment of opportunities for action concerns (1) overall assessment, (2) subjectively relevant activities, and (3) activities that promote health (based on Thomasma 1984; Mittelstadt, Fairweather, McBride, & Shaw 2011).

Life satisfaction (reactive): Life satisfaction refers to an internal norm that is formed in comparison with the social environment and one's own ideals/goals. This concerns both the specific health situation and one's own life as a whole (based on Diener, Emmons, Larsen & Griffin 1985; Frieswijk, Buunk, Steverink & Slaet 2004). An important part of life satisfaction is self-esteem, Self-esteem is an evaluative attitude towards the self in relation to one's own life as a whole and based on assumptions about oneself, which are also based on health-specific factors in the health context (based on Demo & Savin-Williams 1992; Schütz & Sellin 2006).

Age(ing)-related self-image (reactive): The age(ing)-related self-image is an evaluative assessment based on proactive analysis of oneself and interaction partners about oneself and one's own age (own development).

Maintaining or improving health:

Subjective state of health (reactive): Health is defined as an ideal-typical positive functional overall condition with bio-psycho-social aspects, which is realized along a continuum to the construct "illness". The subjective state of health is defined as a momentary perception and evaluation of one's own health. It is functional in general as well as with regard to meaningful activities (based on Hilfebrandt & Kickbusch 2000; Reichard, Alricsson & Werner 2008; Silva et al. 2018; Lawton & Brody 1969).

Health control & competence (reactive): The subjective assessment of self-control, control over others and the environment so that the risks of adverse events are appropriately handled to avoid occurrence. This relates in particular to the perceived likelihood that negative harm to life and health occurs as a result of a hazard (based on Schwartz et al. 2012; Gustafsod 2006; Gorse, Johnston & Pritchard 2012). Health competencies refer to health-promoting behavior that is related to maintaining, restoring, and improving health. The adoption of these measures refers to the attitude and actions with which the individual approaches these measures, and is particularly evident in goal-oriented actions or refraining from actions (e.g. health information seeking) (based on Zielegmann 2002; Graffigna et al. 2017; Lawton & Brody 1969).

Health-promoting behavior (reactive): Health-promoting behavior refers to behavior that is related to maintaining, restoring, and improving health. The adoption of these measures refers to the attitude and actions with which the individual approaches these measures, and is particularly evident in goal-oriented actions or refraining from actions (e.g. health information seeking) (based on Zielegmann 2002; Graffigna et al. 2017; Lawton & Brody 1969).

Social Goals

Promotion of inclusion and participation:

Social interaction (reactive): Social interaction denotes interrelated actions of two or more individuals, e.g. in the form of linguistic communication. Particularly, the focus is on satisfaction with the frequency of interaction, the number of social contacts, and the quality of the interaction (based on Brockhaus Enzyklopädie 1989:560).

Social participation (reactive): Social participation is defined as the degree of subjective participation in society in the sense of a sense of belongingness, participation in subjectively relevant social activities, and the necessary resources and opportunities (based on UNECE 2010:2).

Digital inclusion (reactive): Accessibility in terms of access to and competence in using digital technologies and the resulting quantity of usage compared to the average population (based on Laudon, Laudon & Schoder 2006:255).

Paid activity of older people (reactive): Subjectively assessed quantity and quality of paid work performed (own development).

Voluntary work of older people (reactive): Subjectively assessed quantity and quality of unpaid, voluntarily performed work such as volunteer activities (own development).

Consideration of ethical criteria during development and implementation:

Consideration of ethical guidelines (non-reactive): The consideration and evaluation of moral actions during the development and use of products and services included, among other things, informed consent, a benefit-risk assessment, and risk minimization measures (based on Gabler 2019).

Freedom of choice regarding service access (reactive): Freedom of choice regarding service access includes the degree of perceived self-determination during the usage of AAL products and services (own development).

Freedom of stigma (reactive): The term “stigma-free” refers to the perceived degree of absence of negative categorization and discrimination based on specific characteristics or attributes that arise from the usage of an AAL solution. This particularly concerns negative attribution due to age(ing) and associated negative stereotypes (based on Goffman 1963; Link & Phelan 2001).

Social System Goals

Improvement of the health system:

Sick leaves (reactive): Disability as a result of illness occurs when someone is unable to work due to illness (own development).

Work accidents (reactive): Work accidents are events that suddenly cause damage to the body from the outside and are related to an accident insured activity in terms of location, time, and cause. The insurance also covers journeys and activities in connection with employment or training. Certain accidents are equated with work accidents, even if they affect persons who are not insured against accidents. These include, for example, accidents while rescuing a person from life-threatening danger or while donating blood, accidents during the deployment of members or helpers of aid organizations. Work accidents that led to outpatient or inpatient medical treatment and rescue transports/emergency operations triggered by work accidents are recorded (based on Gabler 2019; AUVA 2019).

Economic and Innovation Goals

Establishment and exploitation of the market potential:

Costs and revenues during development and market launch (non-reactive): Costs are defined as the use or consumption of production factors valued in the form of money (e.g. quantity of input factors or time), which arises within a certain period of time (e.g. months or years). The term “revenues” denotes the generation and utilization of goods and services within a specific accounting period that is performance-related and valued in the form of money (based on Hoitsch & Lingnau 2002:16; von Känel 2008:22).

Market potential (non-reactive): Market potential is defined as the capacity of a market and the total possible sales volumes of a market for a specific product or service. The market potential forms the upper limit for the market volume (based on Gabler 2018).

Willingness to pay (reactive): This refers to the maximum price at which a consumer is willing to buy a unit of a good (based on Jedidi & Jagpal 2009:40).

Business feasibility:

Investment, installation, and de-installation costs (non-reactive): Investment and installation costs include costs for the usage of longer-term assets such as machines, buildings, but also for initial equipment, spare parts, computer systems, etc. De-installation costs arise after the end of use of the longer-term assets when they are no longer needed (based on Gabler 2018).

Operating materials and maintenance costs (non-reactive): Operating and maintenance costs refer to the consumption of raw materials, auxiliary and operating materials, externally sourced primary products as well as personnel costs for the operation and maintenance of AAL products and components that are valued in the form of money. A distinction is made between performance-variable direct and overhead costs and performance-fixed costs (based on von Känel 2008:150).

Human assistance costs (non-reactive): Human assistance costs refer to the consumption of raw materials, auxiliary and operating materials, externally sourced primary products, and personnel costs for human assistance in the usage of AAL products and components that are valued in the form of money. This includes, among other things, user training as well as support and service information. A distinction is made between performance-variable direct and overhead costs and performance-fixed costs (based on von Känel 2008:150).

Financial burden for users (non-reactive): Periodised expenditure valued in the form of money of a primary, secondary or tertiary user in a periodized accounting period for the usage of AAL products and components (based on Gabler 2018).

Overall economic, financial sustainability:

Economic potential from increased labor market participation and voluntary activity (non-reactive): Quantification and economic evaluation of increased labor market participation or volunteering due to the AAL solution (own development)

Design and Technology Goals

Acceptance and user experience:

Subjective intention of use (reactive): Subjective intention of use is the behavioral intention of a person to actually use a specific AAL solution for a purpose envisaged in its development (based on Davis 1989; Venkatesh & Bala 2008).

Pragmatic user experience (reactive): User experience is defined as the evaluative perception of an AAL solution by a person resulting from the use and/or the expected use of a system. It concerns functional aspects, especially perceived usability and usefulness (based on ISO 9241-210:2010; Hartsin & Pyla 2012; Raisamo et al. 2012).

Hedonic user experience (reactive): User experience is defined as the evaluative perception of an AAL solution by a person resulting from the use and/or the expected use of a system. The hedonic level especially concerns the emotional impact (based on ISO 9241-210:2010; Hartsin & Pyla 2012; Raisamo et al. 2012).

Stigma-free design (reactive): Freedom of stigma refers to the perceived degree of absence of negative categorization and discrediting based on specific characteristics or attributes that arise from the usage of an AAL solution. This particularly concerns negative attribution due to age(ing) and related negative stereotypes (based on Goffman 1963; Link & Phelan 2001).

Active/Passive usage (non-reactive): Active usage is defined as usage during which users consciously interact with a system (voluntary and controlled input or output). Passive usage is defined as usage during which users do not consciously interact with the system even though it is active (own development).

Safe handling and protection of data:

Privacy from user perspective (reactive): Privacy from the user's perspective concerns the individual perception of the extent of control over data that the user considers to be personal data. This relates to risk assessments of unauthorized access, unauthorized re-use, concerns that protection against intentional and accidental errors is inadequate, and the extent of data collection (based on Smith, Milberg & Burke 1996; Clarke 1999; Ackerman & Mainwaring 2005; Bélanger & Crossler 2014).

Quality of the technical solution:

Error data (non-reactive): An error is an unexpected system status that results in the inability to perform an intended function. An error can be software-related or hardware-related (based on Butterfield & Ngondi 2016a; Butterfield & Ngondi 2016b).

4.1. Questionnaire Instrument for Users of AAL Solutions (Reactive Data Collection)

Notes on the use of questionnaires and the avoidance of process errors

The questionnaire was constructed for usage with older users whose health shall be maintained or improved with the help of the AAL solution. It takes about 20 minutes to answer the full questionnaire which can be classified as adequate for the target group. The questionnaire was constructed for written surveys (paper or digital) for independent interviewing. If the questionnaires are used in contexts where researchers or examiners are present, they should keep their distance in order to signal to the respondents that they do not look at their answers. If questions arise, for example, due to comprehension problems, the examiners should react with as much reserve as possible, suggest to the test persons that there are no wrong answers and, in case of doubt, only paraphrase the formulations. However, they should certainly not suggest answers so as not to influence the results. The layout of the questionnaires should be kept constant at all survey times and illustrations should be avoided. In the case of oral questioning, the answer items should be read aloud, whereby in the case of scales all answer points should be verbalized at least once, and at least the endpoints and the number of points should be mentioned. The possibility of answers is thereby put in front of the first question with the explanation that the respondent should rate the following statement (for the first question: “On a scale of one to five, where one means ‘do not agree at all’, two means ‘rather disagree’, three means ‘neither’, four means ‘rather agree’ and five means ‘completely agree’, how would you rate the following statements:”; and then: “On a scale of one to five, where one means ‘strongly disagree’ and five means ‘strongly agree’, how would you rate the following statements:”). We recommend giving preference to written survey modes. However, in any case, make sure that the mode is not varied over different survey times.

The questionnaire captures the subjective assessment of older users of the status quo or, in the case of retrospective questions, of the last four weeks prior to the time of the survey. It is, therefore, suitable for a variety of research designs and allows, for example, to measure effects over time or to make comparisons with a control group. The measurements of the fulfillment of design and technology goals as well as the items on willingness to pay and freedom of choice regarding service access, which are not presented in the case of (as yet) non-existent technology usage (e.g. control group, measurement of the baseline in the case of pre-post designs), form an exception here.

Instructions for the participants on answering the questions

General instruction

Thank you very much for participating in this survey.

We would like to ask you to complete the following questionnaire. The questions relate to your personal assessments of your health, your well-being, of health care and work or voluntary activities as well as your approach to digital technologies in general and to *<technology>* in particular.

It takes about 20 minutes to complete the questionnaire. Please make sure to answer all questions. Please read each question carefully before answering. There are no right or wrong answers. If you have any questions about this questionnaire, please contact the examiner in charge.

Interim instructions

The scale “Subjectively relevant activity level“ is introduced with the following instruction: The following questions refer to your general and health-related well-being. Now please think of activities in your life that you personally feel are particularly important, that do you good or that you experience as meaningful. Write down three such activities in the corresponding “activity” fields and then rate the statements for each activity.

Items “voluntary work”, “paid activity”, “sick leaves”, and “work accidents” refer to employment and are introduced with the following instruction: The following questions refer to your level of employment (voluntary and professional activities). Please indicate the answers that apply to you.

Items

Table 37: Items of the instrument for the evaluation of AAL technologies in the area of being active & human potential

No.	Item	Subscale
SRA1, SRA4, SRA7	I am satisfied with the degree to which I can carry out the activity myself.	Subjectively relevant activity level
SRA2, SRA5, SRA8	I am satisfied with my mental abilities to carry out the activity.	Subjectively relevant activity level
SRA3, SRA6, SRA9	I am satisfied with my physical abilities to carry out the activity.	Subjectively relevant activity level
AS1	I can make self-determined decisions in my life.	Autonomy & self-determination
AS2	I can decide for myself which activities that are important to me personally I undertake.	Autonomy & self-determination
AS3	I can decide for myself which activities that are important for my voluntary work or paid work I undertake.	Autonomy & self-determination
LS1	I am generally satisfied with my life.	Life satisfaction
LS2	When I think of my ideals and goals, I am satisfied with my life.	Life satisfaction
LS3	Compared to other people around me, I am satisfied with my life.	Life satisfaction
LS4	When I think of my ideals and goals, I am satisfied with my voluntary or paid work.	Life satisfaction
LS5	Compared to other people around me, I am satisfied with my voluntary or paid work.	Life satisfaction
ARSI1	Compared to my age in years, others perceive me as young.	Age(ing)-related self-image
ARSI2	Compared to my age in years, I perceive myself as young.	Age(ing)-related self-image
LS6	In general, I am satisfied with myself.	Life satisfaction
LS7	I would not want to change anything about myself.	Life satisfaction

No.	Item	Subscale
LS8	I am proud of myself.	Life satisfaction
LS9	I am proud of my voluntary or paid work.	Life satisfaction
SSH1	Concerning my physical abilities, I feel rather...	Subjective state of health
SSH2	Concerning my mental abilities, I feel rather...	Subjective state of health
SSH3	Concerning my social well-being, I feel rather...	Subjective state of health
HCS1	I feel safe.	Health control & competence
HCS2	I think I can keep risks to my health well under control.	Health control & competence
HCS3	I think I can control well whether my life is at risk.	Health control & competence
HCS4	I consciously take actions that promote my health (e.g. sports or healthy eating).	Health control & competence
HCS5	I consciously refrain from actions that are harmful to my health (e.g. smoking).	Health control & competence
HCS6	I inform myself about what behavior is considered healthy or harmful to health.	Health control & competence
SI1	I am satisfied with the frequency with which I am in contact with other people.	Social interaction
SI2	I feel part of society.	Social interaction
SI3	I am satisfied with the number of people I am in contact with.	Social interaction
SP1	I have the opportunity to participate in social activities that are important to me.	Social participation
SP2	I am satisfied with the quality of interaction with my personal contacts.	Social participation
SP3	I feel like I belong to a group (e.g. neighborhood, family, sports club).	Social participation
DI1	Compared to other people around me, I have access to digital technologies.	Digital Inclusion
DI2	Compared to other people around me, I have the skills to use digital technologies.	Digital Inclusion
DI3	Compared to other people around me, I am satisfied with the frequency with which I use digital technologies.	Digital Inclusion
WTP1	Now think of <technology>, at what purchase price would this product be too expensive for you?	Willingness to pay
SIU1	How often will you use <technology> in the next year?	Subjective intention of use
PUX1	The usage of <technology> is simple.	Pragmatic user experience
SFD7	<technology> emphasize my weaknesses.	Stigma-free design
SFD1	When I use <technology>, I feel old.	Stigma-free design
HUX1	I enjoy using <technology>.	Hedonic user experience
SFD3	People around me perceive me as old when they learn that I use <technology>.	Hedonic user experience
HUX1	I like using <technology>.	Stigma-free design
PUX2	The usage of <technology> supports me in my daily life.	Pragmatic user experience

No.	Item	Subscale
SFD5	I think that people see me in a different, worse light when they learn that I use <technology>.	Stigma-free design
SFD6	I do not want others to know that I use <technology>.	Stigma-free design
PUX3	The <technology> are useful to me.	Pragmatic user experience
SFD4	I am ashamed to use <technology>.	Stigma-free design
FC1	I can decide for myself whether I use <technology>.	Freedom of choice regarding service access
FC2	I can decide for myself how often I use a <technology>.	Freedom of choice regarding service access
PR1	It is likely that someone accesses my <technology> data without permission.	Privacy
PR2	It is likely that someone uses my <technology> data without permission for purposes with which I disagree.	Privacy
PR3	It is likely that my <technology> data is not sufficiently protected due to an error.	Privacy
VW1	How many hours did you spend on voluntary work?	Voluntary work
VW2	Voluntary work is a valuable activity to me.	Voluntary work
VW3	I am satisfied with the time I spend on voluntary work.	Voluntary work
PA1	How many hours did you spend on paid work?	Paid activity
PA2	Paid work is a valuable activity to me.	Paid activity
PA3	I am satisfied with the time I spend on paid work.	Paid activity
SL1	In the past four weeks, I have not been able to do my voluntary or paid work due to illness.	Sick leaves
SL2	On how many days in total?	Sick leaves
WA1	In the past four weeks, I have had an accident in the course of my voluntary or paid work.	Work accidents
WA2	How many accidents in total?	Work accidents

Answer specifications

Five-point response format with the options 1 = strongly disagree, 2 = rather disagree, 3 = neither, 4 = rather agree, 5 = strongly agree

Exceptions:

- Items SSH1, SSH2, SSH3: Five-point response format with the options 1 = sick to 5 = healthy
- Item WTP1: From a purchase price of ___ euros
- Item SIU1: Six-point response format with the options 1 = never, 2 = less often than once a month, 3 = monthly, 4 = weekly, 5 = daily, 6 = several times a day
- Item SU3: open (text)
- Items VW1, PW2, WA2: open (numbers)

Evaluation notes

For indicators that are measured by several items (scales), scale averages are to be formed. Thereby the response values of the assigned items are added up and divided by the number

of items. For example, for the scale *autonomy and self-determination*, the values of the items AS1, AS2, and AS3 are added together and then divided by three. The following list shows all items per multi-item subscale:

- Age(ing)-related self-image: ARSI1, ARSI2
- Autonomy & self-determination: AS1, AS2, AS3
- Digital inclusion: DI1, DI2, DI3
- Health control and competence: HCS1, HCS2, HCS3, HCS4, HCS5, HCS6
- Hedonic user experience: HUX1, HUX2
- Life satisfaction: LS1, LS2, LS3, LS4, LS5, LS6, LS7, LS8, LS9
- Paid activity: PA2, PA3
- Pragmatic user experience: PUX1, PUX4, PUX5
- Privacy: PR1, PR2, PR3
- Social interaction: SI1, SI2, SI3
- Social participation: SP1, SP2, SP3
- Stigma-free design: SFD1, SFD3, SFD4, SFD5, SFD6, SFD7
- Subjective state of health: SSH1, SSH2, SSH3
- Subjectively relevant activity level: SRA1, SRA2, SRA3, SRA4, SRA5, SRA6, SRA7, SRA8, SRA9
- Voluntary work: VW2, VW3

In general, missing values should be avoided in the survey. In the case of an online survey, it is recommended to make answering the items compulsory. Furthermore, we recommend that an evaluation is only carried out when at least three questionnaires have been completed in order to avoid violation of anonymity. It must be noted that the principal component analyses showed several cross-loadings occurred. However, these cross-loadings are in line with the definitions of the indicators, but we recommend calculating intercorrelations of the respective scales. In the questionnaire instrument, the respective indicators are operationalized by single or multiple items. For the individual items, we recommend calculating mean values or comparing the absolute numbers. In principle, high values stand for strong agreement and low values for weak agreement.

4.2. Collection of Key Figures (Non-reactive Data Collection)

Consideration of Ethical Guidelines

Definition:
The consideration and evaluation of moral actions during the development and usage of products and services include, among other things, informed consent, a benefit-risk assessment, and measures to minimize risk.

Source of data:
R&D performing institution/company/product developers

The developers or project teams can provide insight into the extent to which ethical guidelines are taken into account in developing and using AAL products and services. The following definition is used for the term ethics (Gabler 2019): “Ethics is the doctrine or theory of action according to the distinction between good and evil. The subject matter of ethics is morality. Greek ethics was empirical and normative at the same time. Today, empirical, descriptive ethics is strictly distinguished from normative ethics, which formulates an ought; this ought makes a claim to be generally binding.”

Object of measurement:
The compliance with ethical guidelines in the development and use of products and services in the field of AAL is measured, taking into account the special needs of older people. At this point, it should be mentioned that this is not exclusively a technology goal, but that exit strategies and similar ethical considerations must also be included.

The following questions can be helpful for the assessment of compliance with ethical guidelines (Felnhofer et al. 2013):

- **Recruitment of participants:**
  - Was the aim of the study explained during recruitment?
- **Benefit-risk assessment:**
  - Have potential risks been identified?
  - Have all steps been taken to minimize the risks?
  - Do the benefits justify the risks?
- **Informed consent:**
  - Was informed consent (IC) given?
  - Did the IC include the following points:
    - aim of the survey
    - duration and procedure of the survey
    - indication of the voluntary nature of participation

        - indication of the possibility to opt-out of the survey at any time and, if so, how to do this
        - explanation of benefits
        - indication of risks
        - contact for further queries
    - Is the information formulated in a comprehensible way and formatted in an age-appropriate way?
    - Has a consent form been signed?
- **Exit strategies**
    - Are there considerations on how to end the project?
    - Is the sustainability of the project ensured beyond its duration?
- **Ethics committee**
    - Has an ethics committee approved the project?

Time of measurement:
Ethical questions must already be clarified or taken into account during the planning or development of AAL products and services. At the latest, however, before the practical application on humans, it should be possible to answer the issues mentioned positively before the test phase.

Measurement mode:
An interrogative process with the help of guidelines as well as codes can accompany the consideration of ethical guidelines. In this context, checklists (see e.g. Felnhofer et al. 2013) can have a supportive effect.

Further notes:
Is there a manual that describes the entire development process and includes ethical considerations?
Another useful tool to include ethical considerations in the development process can be the Gender Sensitive Research Cycle (European Commission DG Research & Innovation 2011:14). The approach is twofold, on the one hand involving men and women equally and thus creating equal opportunities. On the other hand, this approach includes “gender” from the beginning to the end, from the project idea to the publication of the results.

Databases and cross-references to country-specific information:

European Union

- Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (Text with EEA relevance, here: Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (Text with EEA relevance)
- Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC Text with EEA relevance (European Parliament and Council of the European Union 24 May 2014, here: Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC Text with EEA relevance)
- Ethics and data protection (European Commission 5 July 2021, here: Ethics and data protection)
- Guidelines 05/2020 on consent under Regulation 2016/679 (European Data Protection Board 4 May 2020, here: Guidelines 05/2020 on consent under Regulation 2016/679)
- Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (Text with EEA relevance, here: Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (Text with EEA relevance.))
- Assessment of the EU Member States' Rules on Health Data in the Light of GDPR (European Commission 2021, here: Assessment of the EU Member States' Rules on Health Data in the Light of GDPR)
- Handbook on European Data Protection Law (Publications Office of the European Union 2018, here: Handbook on European data protection law

Austria (for country-specific information see page 43)

- Digital Health Laws and Regulations 2021 (Global Legal Group 2021, here: Austria: Digital Health Laws and Regulations 2021)

Belgium (for country-specific information see page 47)

- Digital Health Laws and Regulations 2021 (Global Legal Group, 2021, here: Belgium: Digital Health Laws and Regulations 2021)

Cyprus (for country-specific information see page 49)

Hungary (for country-specific information see page 51)

Italy (for country-specific information see page 54)

- Digital Health Laws and Regulations 2021 (Global Legal Group 2021, here: Italy: Digital Health Laws and Regulations 2021)

Luxembourg (for country-specific information see page 57)

Netherlands (for country-specific information see page 61)

Norway (for country-specific information see page 64)

- Data Protection Laws and Regulations 2021 (Global Legal Group 2021, here: Norway: Data Protections Laws and Regulations 2021)
- Guidelines by The Norwegian National Research Ethics Committee for Medical and Health Research (NEM) (Norwegian National Research Ethics Committee for medical and health research 2019, here: Guidelines by The Norwegian National Research Ethics Committee for medical and health research (NEM))

Poland (for country-specific information see page 67)

Portugal (for country-specific information see page 70)

Romania (for country-specific information see page 72)

Slovenia (for country-specific information see page 76)

- Data Protection Laws and Regulations 2021 (Global Legal Group 2021, here: Slovenia: Data Protections Laws and Regulations 2021)

Spain (for country-specific information see page 79)

- Digital Health Laws and Regulations 2021 (Global Legal Group 2021, here: Spain: Digital Health Laws and Regulations 2021)

Switzerland (for country-specific information see page 81)

- Digital Health Laws and Regulations 2021 (Global Legal Group 2021, here: Switzerland: Digital Health Laws and Regulations 2021)

State of Health

Definition:
In addition to the subjective state of health (based on Erhart et al. 2006:321ff), characterized by an independent assessment of one's own health, health should also be surveyed. For example, it can be determined via vital parameters (e.g. pulse, blood pressure, body temperature, respiration, etc.); clinical parameters (e.g. pulmonary function capacity, etc.); laboratory parameters (e.g. sodium, potassium, blood count, etc.); the number of risk factors; degrees of disability and restriction or diagnosed diseases.

Source of data:
Users and/or electronic health records (EHRs)

Concerning AAL solutions, the project team can partly collect objective health data directly from the users. The various devices provide vital and laboratory parameters. The users can also give insight into anonymized medical history via electronic health records (EHRs).

Object of measurement:
For measuring the objective state of health, for example, vital parameters, laboratory parameters, diagnosed diseases, and risk factors from the user's medical history and automated recording can be used. At least two measurements are necessary to establish comparisons. The following table gives an overview of potential measurement parameters and the distinction between the subjective and objective state of health.

Table 38: Subjective and objective state of health

Subjective state of health	e.g., own assessment of my health today
Objective state of health	Vital parameters (e.g., pulse, blood pressure, body temperature, respiration, etc.)
Objective state of health	Clinical parameters (e.g., oxygen saturation, pulmonary function capacity, etc.)
Objective state of health	Laboratory parameters (e.g., sodium or potassium concentration, blood count, etc.)
Objective state of health	Number and type of risk factors (e.g., smoking, alcohol, exercise) Degree of disability and restriction (e.g. level of care allowance)
Objective state of health	Diagnosed (pre-existing) diseases

Source: own representation

For the application area of being active, for example, the number and type of risk factors can be measured (e.g., alcohol, smoking, exercise). By recording the degree of disability and restriction, it is possible to measure the extent to which people can continue to be active.

Time of measurement:
In order to be able to compare the measurement results, several measurement dates are appropriate. Measurement should be arranged before the introduction of the AAL solution in order to be able to present potential changes after the introduction of the technology. Ideally, an intervention and control group are formed and continuous measurements are performed over the entire course of the project.

Measurement mode:
Measurement is made by manual reading of the devices or the documentation or by automatic evaluations of the laboratory devices. Medical professionals should be consulted for the interpretation of data.

Further notes:
Previously, there were discussions with experts and within the research team as to whether the indicators subjective health status and objective health status are comparable and which indicator is best suited for describing the state of health and should therefore be included in the indicator set.

In a large study (n=16,074) in China, Wu et al. (2013) were able to prove that the subjective state of health is consistent with the objective state of health and can be used as a general benchmark for the common population. Even among people over 60 years of age, the subjective state of health is comparable to the objective state of health according to a Chinese study (n=1,096) by Meng et al. (2014).

Nevertheless, the project team suggests collecting relevant data on the state of health subjectively and objectively for the respective AAL solution if possible. In the AAL setting, invasive measurements should be avoided. These are exclusively located in clinical settings.

Databases and cross-references to country-specific information:

European Union

- Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (Text with EEA relevance, here: Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (Text with EEA relevance)
- Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC Text with EEA relevance (European Parliament and Council of the European Union 24 May 2014, here: Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC Text with EEA relevance)
- Ethics and data protection (European Commission 5 July 2021, here: Ethics and data protection)
- Guidelines 05/2020 on consent under Regulation 2016/679 (European Data Protection Board 4 May 2020, here: Guidelines 05/2020 on consent under Regulation 2016/679)
- Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (Text with EEA relevance, here: Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (Text with EEA relevance.))
- Assessment of the EU Member States' Rules on Health Data in the Light of GDPR (European Commission 2021, here: Assessment of the EU Member States' Rules on Health Data in the Light of GDPR)
- Handbook on European Data Protection Law (Publications Office of the European Union 2018, here: Handbook on European data protection law

Austria (for country-specific information see page 43):

- Electronic health records, i.e., Elektronische Gesundheitsakte (see here: ELGA)
- Digital Health Laws and Regulations 2021 (Global Legal Group 2021, here: Austria: Digital Health Laws and Regulations 2021)

Belgium (for country-specific information see page 47)

- Electronic health records, i.e., Summarized Electronic Health Record (see here: SUMHER)
- Digital Health Laws and Regulations 2021 (Global Legal Group 2021, here: Belgium: Digital Health Laws and Regulations 2021)

Cyprus (for country-specific information see page 49)

Hungary (for country-specific information see page 51)

- Electronic health records, i.e., Elektronikus Egészségügyi Szolgáltatási Tér (see here: EESZT)

Italy (for country-specific information see page 54)

- Electronic health records, i.e., Fascicolo Sanitario Elettronico (see here: Fascicolo Sanitario Elettronico)
- Digital Health Laws and Regulations 2021 (Global Legal Group 2021, here: Italy: Digital Health Laws and Regulations 2021)

Luxembourg (for country-specific information see page 57)

- Electronic health records, i.e., Dossier de soins partagé (see here: DSP)

Netherlands (for country-specific information see page 61)

- Electronic health records, i.e., Persoonlijke gezondheidsomgeving (see here PGO)

Norway (for country-specific information see page 64)

- Electronic health records, i.e., Digital Health Services (see here: HELSENORGE)
- Data Protection Laws and Regulations 2021 (Global Legal Group 2021, here: Norway: Data Protections Laws and Regulations 2021)
- Guidelines by The Norwegian National Research Ethics Committee for Medical and Health Research (NEM) (Norwegian National Research Ethics Committee for medical and health research 2019, here: Guidelines by The Norwegian National Research Ethics Committee for medical and health research (NEM))

Poland (for country-specific information see page 67)

- Electronic health services and records, i.e. E-usługi (see here: E-usługi)

Portugal (for country-specific information see page 70)

- Electronic health records, i.e., ePortugal (see here: ePortugal)

Romania (for country-specific information see page 72)

- lectronic health records, i.e., Dosarul Electronic de Sănătate (see here: DES)

Slovenia (for country-specific information see page 76)

- Electronic health records, i.e., zVEM (see here: zVEM)
- Data Protection Laws and Regulations 2021 (Global Legal Group 2021, here: Slovenia: Data Protections Laws and Regulations 2021)

Spain (for country-specific information see page 79)

- Electronic health records, i.e., É-Saúde (see here: É-Saúde)
- Digital Health Laws and Regulations 2021 (Global Legal Group 2021, here: Spain: Digital Health Laws and Regulations 2021)

Switzerland (for country-specific information see page 81):

- Electronic health records, i.e., Elektronisches Patientendossier (see here: EPD)
- Digital Health Laws and Regulations 2021 (Global Legal Group 2021, here: Switzerland: Digital Health Laws and Regulations 2021)

Active/Passive Usage

Definition:
Active usage is when users consciously interact with a system (voluntary and controlled input or output). Passive usage is defined as when the system is active but the users do not consciously interact with it.

Source of data:
Users or software

The respective developed software serves as the data source. Within the framework of the development of the AAL solution, care must be taken to ensure that this solution's active and passive usage can be recorded by the software.

Object of measurement:
During project planning, the research team must determine what is understood as active usage or passive usage in the concrete case of application. Active usage is, for example, when users actively use the tablet to chat, play games or look at their health data. An example of passive usage is the pedometer, which is integrated into the smartwatch and runs in the background.

Time of measurement:
Data on usage should be collected continuously so that changes over time can be accurately represented. If possible, researchers should collect data over the entire project period.

Measurement mode:
How data can be retrieved depends on the respective project structure and software. Usually, the recorded activity data are stored in databases, which can then be readout.

Further notes:
Data on active/passive usage allows concluding the usage behavior of participants. Davis et al. (1989) have shown with the technology acceptance model that using technology is centrally dependent on two variables: perceived usefulness and perceived ease-of-use. The usage behavior subsequently influences whether and which effects the technical system has on everyday life and the subjective quality of life of the target group (Kada et al. 2017:23).

Databases and cross-references to country-specific information:

European Union

- Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (Text with EEA relevance, here: Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (Text with EEA relevance)
- Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC Text with EEA relevance (European Parliament and Council of the European Union 24 May 2014, here: Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC Text with EEA relevance)
- Ethics and data protection (European Commission 5 July 2021, here: Ethics and data protection)
- Guidelines 05/2020 on consent under Regulation 2016/679 (European Data Protection Board 4 May 2020, here: Guidelines 05/2020 on consent under Regulation 2016/679)
- Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (Text with EEA relevance, here Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (Text with EEA relevance.))
- Assessment of the EU Member States' Rules on Health Data in the Light of GDPR (European Commission 2021, here Assessment of the EU Member States' Rules on Health Data in the Light of GDPR)
- Handbook on European Data Protection Law (Publications Office of the European Union 2018, here Handbook on European data protection law

Austria (for country-specific information see page 43)

- Digital Health Laws and Regulations 2021 (Global Legal Group 2021, here: Austria: Digital Health Laws and Regulations 2021)

Belgium (for country-specific information see page 47)

- Digital Health Laws and Regulations 2021 (Global Legal Group 2021, here: Belgium: Digital Health Laws and Regulations 2021)

Cyprus (for country-specific information see page 49)

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Italy (for country-specific information see page 54)

- Digital Health Laws and Regulations 2021 (Global Legal Group 2021, here: Italy: Digital Health Laws and Regulations 2021)

Luxembourg (for country-specific information see page 57)

Netherlands (for country-specific information see page 61)

Norway (for country-specific information see page 64)

- Data Protection Laws and Regulations 2021 (Global Legal Group 2021, here: Norway: Data Protections Laws and Regulations 2021)
- Guidelines by The Norwegian National Research Ethics Committee for Medical and Health Research (NEM) (Norwegian National Research Ethics Committee for medical and health research 2019, here: Guidelines by The Norwegian National Research Ethics Committee for medical and health research (NEM))

Poland (for country-specific information see page 67)

Portugal (for country-specific information see page 70)

Romania (for country-specific information see page 72)

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- Data Protection Laws and Regulations 2021 (Global Legal Group 2021, here: Slovenia: Data Protections Laws and Regulations 2021)

Spain (for country-specific information see page 79)

- Digital Health Laws and Regulations 2021 (Global Legal Group 2021, here: Spain: Digital Health Laws and Regulations 2021)

Switzerland (for country-specific information see page 81)

- Digital Health Laws and Regulations 2021 (Global Legal Group 2021, here: Switzerland: Digital Health Laws and Regulations 2021)

Error Data

Definition:
Error data is divided up into two groups: subjective and objective errors. A subjective error occurs in the case of an unsuccessful attempt to perform a task, regardless of where the cause is subjectively located (software, hardware, user). An objective error or unexpected system status occurs when an intended function cannot be carried out. Such an error can be software-related or hardware-related.

Source of data:
Logfile of the developed software/survey among users in a laboratory setting through usability test/evaluation of helpdesk data

In the first step, the research team has to identify the unexpected behavior (the error) in the log file or database or observe it in a laboratory setting. In the next step, researchers can evaluate the data/observations and subsequently analyze this information.

Object of measurement:
The number and extent of subjective and objective errors are measured. What exactly constitutes an error must be determined individually by the research team for each project. The errors can be divided into subjective errors triggered by the user, e.g. by clicking incorrectly in the software, incorrect configuration of wearables, etc., and objective errors, e.g. no GPS reception on the smartwatch. Furthermore, the project team can categorize the different errors, e.g. severity of the error, system aspects affected, reproducibility, error triggered by software, hardware, or user.

Time of measurement:
Typically, error data are recorded continuously and changes can be accurately represented over a period of time. If possible, researchers should collect, evaluate and analyze the entire measurement period.

Measurement mode:
How data are measured must be adapted individually. The techniques of data validation (checking the entered or recorded data for completeness and usefulness) & pattern recognition (automatic recognition of patterns, regularities, repetitions, or laws) can support this process (ÖNORM 2011:5ff).

In the case of subjective error data, e.g. collected through the number of calls to the helpdesk, these can be analyzed according to the type, extent, and duration of the error. The procedure could look like this, for example: First, a process is defined. Afterward, an initial check takes place in the laboratory setting to see whether the test persons adhere to the process as planned (similarity to users is important). Parallel to this, an evaluation is carried out by experts, and any errors are corrected. Finally, the product/service can be rolled out. Also during the

field test, there should be a constant evaluation of possible errors and potential corrections of these.

Further notes:
Here, reference can be made to EN ISO 9241-110 (2006:4-8f), in which the seven dialogue principles for interactive systems are defined. One such principle is fault tolerance. In this context, Hofmann (2008) points out that a system that acts interactively must demonstrate fault tolerance to its user. “This means that, on the one hand, it prevents the user from making mistakes - for example, by means of clearly understandable security questions, but on the other hand, it constructively supports the user in the event of an error so that the error can be rectified without too much effort.

Within the framework of the evaluation of the indicator, it is therefore also relevant to constructively discuss the causes of the errors that have occurred as well as improvement potentials. Accordingly, updates of the software or the like to improve the usability of the system are also to be treated as data discontinuity in the measurement period.

A potential parallel reactive questioning of the users about the errors that occurred can broaden understanding of the AAL solution and better explain user behavior. The results about the errors that occurred and their correction should be incorporated in training and documentation.

The ISO 9241-210 2010 standard provides many checklists that can support the process of designing usable interactive systems. These checklists include, for example, items on principles of human-centered design, planning of human-centered design, and human-centered design activities.

Databases and cross-references to country-specific information:

European Union

- Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (Text with EEA relevance, here: Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (Text with EEA relevance)
- Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC Text with EEA relevance (European Parliament and Council of the European Union 24 May 2014, here: Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC Text with EEA relevance)
- Ethics and data protection (European Commission 5 July 2021, here: Ethics and data protection)
- Guidelines 05/2020 on consent under Regulation 2016/679 (European Data Protection Board 4 May 2020, here: Guidelines 05/2020 on consent under Regulation 2016/679)
- Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (Text with EEA relevance, here: Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (Text with EEA relevance.))
- Assessment of the EU Member States' Rules on Health Data in the Light of GDPR (European Commission 2021, here: Assessment of the EU Member States' Rules on Health Data in the Light of GDPR)
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- Digital Health Laws and Regulations 2021 (Global Legal Group 2021, here: Switzerland: Digital Health Laws and Regulations 2021)

Human Assistance Costs

Definition:
Human assistance costs are defined as consumption of raw materials, auxiliary and operating materials, externally sourced primary products (material costs), and personnel costs for human assistance in the usage of AAL products and components. This includes, among other things, user training as well as support and service activities.

Source of data:
Providers of the AAL product or service and secondary data and/or official statistic authorities

The costs or price of an AAL product or service includes all costs and follow-up costs incurred by the user from the usage of an AAL product or service (based on Scharf, Schubert & Hehn 2015:337). This includes user training and support as well as service information. This measuring guide focuses on the immediate costs that arise from the use of an AAL solution. Medium- to long-term costs are discussed in more detail in the measuring guide for operating materials and maintenance costs.

If the provider of the AAL product or service does not provide the relevant information, secondary data from official statistics can be used for approximating the data needed. The data is broken down by industry (Statistical classification of economic activities in the European Community; i.e., NACE) and/or by occupation (International Standard Classification of Occupations; i.e.; ISCO) in the respective countries. In the case of international comparative analyses, it is essential to take the respective national purchasing power standard (PPS) into account in the analysis.

Object of measurement:
Human assistance costs are direct costs that can arise when using the AAL product or the AAL service, e.g. training of users, service information at helpdesks, or support services. The research project IntegrAAL distinguishes three categories of assistance costs depending on the necessary qualification of the respondents (based on Kumpf et al. 2014:93f):

- Level A: Assistance work can be performed by any person
- Level B: Assistance work does not require specific qualification, but good physical general condition
- Level C: Assistance work requires specific professional qualifications, e.g. doctors, certified caregivers, computer technicians

A potentially helpful categorization of assistance costs is to be determined by the project team for the specific AAL application. Costs for human assistance are not only characterized by personnel costs. For example, when a qualified nurse carries out diabetes training, he/she will need blood glucose meters, blood glucose test strips, training material, etc.

Time of measurement:
Costs for human assistance of the application of the AAL products and services should be recorded on the one hand for specific time intervals (e.g. month of commissioning) and on the other hand for the total duration of the project (based on OECD 2018:152).

Measurement mode:
Data should be requested from the AAL product or service providers, as they are most qualified to provide information on the respective costs or can draw on empirical values. Data can be collected in different ways, e.g. with a paper or online questionnaire, by telephone, or through personal interviews (based on OECD 2018:218).

Databases and cross-references to country-specific information:

European Union and EFTA

- Database - Labour Market (incl. LFS). (n.d.). Eurostat (see here: Earnings)
- Database - Purchasing power parities. (n.d.). Eurostat (see here: Purchasing power parities)

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Financial Burden for Users

Definition:
Periodized expenditure valued in the form of money by a primary, secondary or tertiary user in a periodized accounting period for the usage of AAL products and components.

Source of data:
Providers of the AAL solution/developers as well as users and secondary data and/or official statistic authorities

The research team collects data from the AAL product or service providers or from the *primary*, *secondary* or *tertiary* users. Primary users are people who benefit directly from AAL, secondary indirect users such as formal and informal health and care service providers, and tertiary users are those who do not use AAL directly but are involved in its organization and financing in some way or other (e.g. political decision-makers, representatives of social and/or private insurance companies).

In international comparative analyses, it is essential to consider the respective national purchasing power standard (PPS) as well as the corresponding Classification of Individual Consumption by Purpose (COICOP) in the analysis.

Object of measurement:
The total financial burden for primary, secondary or tertiary users includes investment and de-investment costs (see **investment, installation and de-installation costs**; e.g. **acquisition costs of the AAL product, installation costs, training costs, and de-installation costs**) as well as costs for ongoing operation and maintenance (see **operating materials and maintenance costs**; e.g. **electricity costs, insurance, repairs or technical operating costs**). Furthermore, additional service costs can arise that are attributable to the AAL product or service. The following table contains a comprehensive presentation of cost positions that should be recorded.

Table 39: Burden categories

Investment costs (and de-investment costs):
Acquisition costs
Installation costs
Training for (end) users and others
De-installation costs (e.g. after project completion, after death, after a change of care type)
Costs of ongoing operation/maintenance:
Technical operating costs
Repairs
Insurances
Electricity costs
Emergency services etc.
Additional service costs (attributable to AAL product)

Source: Kumpf et al. 2014:92ff; own representation

Time of measurement:
Costs should be reported for the entire period when the user uses the AAL product or service. This approach is supposed to ensure an exact allocation of costs; regardless of the actual outgoing payment (based on OECD 2018:152).

Measurement mode:
Data should be requested from the AAL product or the AAL service providers, as they are most qualified to provide information on the respective costs or can draw on empirical values. However, certain parameters, such as electricity consumption, possibly need to be requested directly from the users. Data can be collected in various ways, e.g. by paper or online questionnaires, telephone, or personal interviews (based on OECD 2018:218).

Further notes:
“Prior to the start of the project, it has to be clarified which form of cost allocation and recording will actually be carried out. AAL projects are usually characterized by specific cost units (funding agencies, non-profit, and other project partners), i.e. in some cases market prices are not charged in projects or market prices are not yet available, which could partly impede a realistic cost calculation.” (based on Kumpf et al. 2014:93ff). If market prices are already available, they should be used to ensure a realistic representation of the financial burden for end users.

Databases and cross-references to country-specific information:

European Union and EFTA

- Database - Labour Market (incl. LFS). (n.d.). Eurostat (see here: Earnings)
- Database - Purchasing power parities. (n.d.). Eurostat (see here: Purchasing power parities)

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Costs and Revenues during Development and Market Launch

Definition:
Costs are defined as the usage or consumption of production factors valued in the form of money (e.g. quantity of input factors or time), which arise within a certain period of time (e.g. months or years).
Revenues denote the performance-related creation of goods and services, valued in the form of money, as well as their utilization within a specific accounting period (based on Hoitsch & Lingnau, 2007:16; von Känel 2008:22).

Source of data:
R&D performing institution/company/product developers and secondary data and/or official statistic authorities

On the one hand, the primary focus of companies is on cost minimization, i.e. the prime costs in the development and production of AAL solutions/components should be as low as possible, and, on the other hand, it is on revenue maximization, so that company profits are developed to the maximum.
The measurement of costs and revenues should take place at the institution/company/product developers carrying out R&D since they bear the responsibility for the costs and are obliged to document these due to applicable legal regulations (based on Ehrlenspiel et al. 2005:5).

If the developer of the AAL product or service does not provide the relevant information, secondary data from official statistics can be used for approximating the data needed. The data is broken down by industry (Statistical classification of economic activities in the European Community; i.e., NACE) and/or by occupation (International Standard Classification of Occupations; i.e.; ISCO) in the respective countries. In international comparative analyses, it is essential to consider the respective national purchasing power standard (PPS) as well as the corresponding Classification of Individual Consumption by Purpose (COICOP) in the analysis.

Object of measurement:
The categories listed in the following table are to be used to determine the **costs** involved in the development and market launch of AAL solutions/components.

Table 40: Categories of R&D expenses

Sum of R&D expenses
Capital expenditure
Land and buildings
Machinery and equipment
Activated computer software
Other products of intellectual property
Current expenses
Personnel expenses
Other current expenses
Operating materials and maintenance costs

Source: Based on OECD (2018:142); own representation

R&D capital expenditure is the gross annual amount paid for the acquisition of assets for the performance of research and development that are used repeatedly or continuously for more than one year. R&D capital expenditures include tangible assets (physical assets such as buildings and facilities or machinery and equipment) and intangible assets (e.g. computer software and other intellectual property products).
Current R&D expenses are composed of R&D-related personnel and other current expenses. Services and goods (including equipment) consumed within one year are included in current expenses. Annual fees or rents for the use of assets should also be considered in current expenses (based on OECD 2018:129).
Personnel expenses include remuneration for employed, non-independent R&D staff, such as annual wages and salaries and any related costs or fringe benefits (e.g. bonus payments, stock options, and holiday pay, in addition to pension and other social security contributions, payroll taxes, and duties, etc.). It is important to consider personnel expenses for employees only to the extent to which they contribute directly to research and development (based on OECD 2018:130).
Other current R&D expenses are defined as purchases and rentals of materials, commodity goods, equipment, and services from private or public institutions that do not fall in the category of investments within a reference year (e.g. water, gas, electricity, specialist books, journals, royalties and license fees for the use of patents and other intellectual property rights, or leasing of capital goods; based on OECD 2018:132). Administrative and overhead costs (e.g. office space, IT and telecommunications, building maintenance, insurance) should also be included in other current expenses and prorated if necessary (based on OECD 2018:133).
The sums of R&D expenditures of a project or product development should be recorded and reported at purchase prices. Purchase prices are prices paid by research institutions and companies without taking into account deductible percentages of VAT and similar taxes. These

reflect the actual costs incurred during the research and development of AAL solutions (based on OECD 2018:136).
With regard to **revenues**, it can be assumed that R&D performing institutions and facilities such as companies, universities, and universities of applied sciences are financed by third-party funds from national or international research funding, by contract research from public and private economy, or by subsidies and financial aid. In some cases, R&D is financed at least partially or exclusively with internal means (equity capital) (based on OECD 2018:149f).
The (imputed) profit or loss for the project duration is calculated from the difference between the revenues related to the time period and the costs to be compared with them (based on von Känel 2008:197).

Time of measurement:
Costs and revenues should be reported for the period in which R&D is conducted and not for the period in which own or third-party funds have been received (based on OECD 2018:152). This is to ensure an exact allocation of costs and revenues to the respective R&D process, regardless of the actual incoming or outgoing payments.

Measurement mode:
Data can be collected in different ways, e.g. with a paper or online questionnaire, by telephone, or through personal interviews. If accessible, data could also be obtained from administrative sources of the public sector (based on OECD 2018:218). Personal coordination with the institution conducting R&D is recommended in any case to avoid misunderstandings.

Further notes:
It must be clarified before and during the course of the project which of the cost parameters presented above are to be recorded. Development costs are particularly difficult to determine, as they are often based on already existing projects. For this reason, only the research and development costs attributable to the project should be recorded if possible.

Databases and cross-references to country-specific information:

European Union and EFTA

- Database - Labour Market (incl. LFS). (n.d.). Eurostat (see here: Earnings)
- Database - Purchasing power parities. (n.d.). Eurostat (see here: Purchasing power parities)

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Switzerland (for country-specific information see page 80)

Operating Materials and Maintenance Costs

Definition:
The consumption of raw materials, auxiliary and operating materials, externally sourced primary products (material costs) as well as personnel costs for the operation and maintenance of AAL products and components valued in monetary terms (based on von Känel 2008:150).

Source of data:
Providers of the AAL product and/or AAL service and secondary data and/or official statistic authorities

The cost or price of an AAL product or service includes all costs and follow-up costs incurred by primary, secondary, or tertiary users from the usage of an AAL product or service (based on Scharf et al. 2015:337). This measurement guide focuses on running costs that arise from the usage of an AAL solution. These particularly include **running costs** for **operating materials and maintenance costs**. **One-off costs** such as **investment, installation, and de-installation costs** or **human assistance costs** are discussed in more detail in another measurement guide.

If the provider of the AAL product or service does not provide the relevant information, secondary data from official statistics can be used for approximating the data needed. The data is broken down by industry (Statistical classification of economic activities in the European Community; i.e., NACE) and/or by occupation (International Standard Classification of Occupations; i.e.; ISCO) in the respective countries. In international comparative analyses, it is essential to consider the respective national purchasing power standard (PPS) as well as the corresponding Classification of Individual Consumption by Purpose (COICOP) in the analysis.

Object of measurement:
Operating materials and maintenance costs are a sub-category of the category “other current expenses” of the indicator “costs and revenues during development and market launch”.
Running costs of operation and maintenance of AAL products and services (e.g. technical operating costs, repairs, insurance, emergency services for a telemonitoring system) should be recorded and reported at purchase prices. Purchase prices are the prices paid by primary, secondary, and tertiary users without taking into account the deductible percentage of VAT and similar taxes. Purchase prices reflect the actual costs incurred by users (based on OECD 2018:136; Kumpf et al. 2014:93).

Any personnel costs that are research-related and associated with the ongoing operation and maintenance of an AAL solution are also to be included in this regard. These costs should be differentiated from personnel costs that are one-off costs, incurring e.g. during the installation or de-installation of an AAL product or service (see **investment, installation, and de-installation costs**).

Time of measurement:
The costs for operation and maintenance should be recorded for specific time intervals (e.g. month of commissioning) as well as for the total duration (based on OECD 2018:152).

Measurement mode:
Data should be requested from the AAL product or service providers, as they are most qualified to provide information on the respective prices or can draw on empirical values. Data can be collected in various ways, e.g. by paper or online questionnaires, telephone, or personal interviews (based on OECD 2018:218).

Further notes:
It must be clarified before and during the course of the project which operating materials and maintenance costs are to be recorded. Particularly in the case of operating materials, there is a possibility that these will be allocated to overhead costs since they are not clearly attributable. Therefore, care should be taken to avoid double counting and/or double billing.

Databases and cross-references to country-specific information:

European Union and EFTA

- Database - Labour Market (incl. LFS). (n.d.). Eurostat (see here: Earnings)
- Database - Purchasing power parities. (n.d.). Eurostat (see here: Purchasing power parities)

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Investment, Installation and De-installation Costs

Definition:
Investment and installation costs are defined as expenses for fixed assets such as machines, buildings but also initial equipment, spare parts, computer systems, etc. as well as associated installation costs (e.g. transport, assembly), which are usually one-off costs. De-installation costs are incurred after the service life when long-term assets are no longer needed (e.g. dismantling, removal, disposal).

Source of data:
R&D performing institution/company/product developers and secondary data and/or official statistic authorities

The cost or price of an AAL product or service includes all costs and follow-up costs incurred by the primary, secondary or tertiary user from the usage of an AAL product or service (based on Scharf et al. 2015:337). This measurement guide focuses on investment, installation, and de-installation costs.

In international comparative analyses, it is essential to consider the respective national purchasing power standard (PPS) as well as the corresponding Classification of Individual Consumption by Purpose (COICOP) in the analysis.

Object of measurement:
Investment, installation, and de-installation costs are a sub-category of capital expenditure or the machinery and equipment of the indicator (see **costs and revenues during development and market launch**).

It is necessary to record any costs for the delivery, assembly, installation, and de-installation (e.g. after the end of a project test phase or the decease of primary end-users) and to assess them at the purchase prices (excluding VAT, etc. where applicable) of primary, secondary or tertiary users monetarily (based on Kumpf et al. 2014:93).

Personnel costs associated with the installation and de-installation of AAL solutions are usually one-off costs and must be assigned to this category. Not included are personnel expenses that are attributed to current expenses (see **current expenses** in **costs and revenues during development and market launch).**

Time of measurement:
Investment, installation, and de-installation costs should be reported for the period in which they are incurred.

Measurement mode:
Data should be requested from providers of the AAL product or the AAL service, as they are most qualified to provide information about the respective costs. Data collection can take place in different ways, e.g. with a paper or online questionnaire, by telephone, or through personal interviews.

Databases and cross-references to country-specific information:

European Union and EFTA

- Database - Labour Market (incl. LFS). (n.d.). Eurostat (see here: Earnings)
- Database - Purchasing power parities. (n.d.). Eurostat (see here: Purchasing power parities)

Austria (for country-specific information see page 43)

Belgium (for country-specific information see page 46)

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Market Potential

Definition:
Market potential is understood as the capacity of a market and the total possible sales volume of a market for a certain product or service. Market potential forms the upper limit for market volume.

Source of data:
Secondary data and secondary data and/or official statistic authorities

On the one hand, AAL technologies are characterized by push factors, in particular by technological progress and the associated development of new products and services. On the other hand, there are pull factors, above all the steady increase in the number of older people, which characterize this market (based on AAL Association 2014:8).

Due to these determinants, there is a very wide range of application areas and thus possible AAL solutions that attempt to increase or at least maintain the quality of life of older people. This results in a very indeterminate market term for AAL instead of a specific term, which can vary depending on the respective area of application of the solution and the therefore heterogeneous users, who differ e.g. in their health deficits. In particular, users influence the potential sales volume of an AAL solution, which needs to be defined in more detail in the next step.

Object of measurement:
Apart from the quantity sold, the possible number of consumers of AAL products and service solutions is one of the basic parameters for determining the market potential.

Consumers are further subdivided into primary users, i.e. people who benefit directly from AAL, secondary users, i.e. indirect users such as formal and informal health and care service providers, and tertiary users who do not use AAL directly but are involved in some way in its organization and financing (e.g. political decision-makers, representatives of social and/or private insurance companies). In the following, some measured quantities are presented that are either directly or indirectly relevant for determining the market potential.

FloTable 41: Measured quantities for determining market potential

Development of the AAL market
Current and potential users: Data on current and potential users (demographic data, user segments/profiles); socio-demographic indicators; socio-economic indicators; internet usage; technology orientation
Market value and size: intensity of usage; distribution rate; income and expenses; main benefits/problems
Market developments and driving forces: information on technology trends; emerging solutions (future products, forecasts, strategy plans, etc.); user perception; expectations; satisfaction
Interoperability and standardization issues: information on adopted/current standards
Development of key players
Number and type of key players and new market entrants: total; by market segment; by classification; by company size; business and marketing measures; sustainable business models; time to market
Development of investments
Number and type of market offensives: start-up companies; mergers and acquisitions; IPOs; support programs; survival rate of start-ups; investments by market segment/type of solution

Source: Based on AAL Association (2014:28); own representation

In addition to the number of potential users, the sales volume of an AAL solution depends primarily on the purchasing power of private and/or public households that pay for the financing of the solution.

In contrast to market potential, the market volume describes the units actually sold (sales) or the corresponding monetary measured values (turnover).

Time of measurement:
Market potential should be calculated for a full calendar year or at least for a precisely defined period of time (e.g. the next 5 years). In addition, the geographical coverage area (e.g. country, federal state) should be defined. This ensures comparability from both a temporal and a geographical perspective and makes the analysis of past and future trends possible.

Measurement mode:
Depending on the indicator chosen, different types of data, i.e. quantitative data, market research data, and qualitative data can be used to determine the respective indicator.

Official statistics and resulting quantitative data are usually of high quality and reliability. Often these are collected transnationally - especially in the European Union (EU) - according to uniform standards so that comparability between the countries is given. These data are particularly suitable for determining demographic trends, health expenditure as a percentage of

the gross domestic product, etc. However, they are often not suitable for the analysis of innovative markets, products, and product segments, which means that the characteristics of a market can only be inadequately represented.

To analyze these, quantitative market research data should therefore be used, but these are often only available to a limited extent and, above all, only against payment. With regard to the survey methods and associated data, it must also be noted that not the same quality criteria apply as, for example, to the national statistical offices.

Compared to quantitative surveys, qualitative surveys such as guided expert interviews, focus group interviews, case studies, etc. are often less structured, which is at the expense of the comparability of results. However, they offer solid and in-depth market information when a specific segment of customers, stakeholders, market scenarios (e.g. depending on socio-demographic characteristics), etc. is to be analyzed.

Databases and cross-references to country-specific information:

European Union and EFTA

- Database - Population and demography. (n.d.). Eurostat (see here: Population and demography)
- Database - Population projections. (n.d.). Eurostat (see here: Population projections)
- Database - Labour Market (incl. LFS). (n.d.). Eurostat (see here: Earnings)
- Database - Digital economy and society. (n.d.). Eurostat. (see here: Digital economy and society)
- Database – Structural business statistics. (n.d.). Eurostat. (see here: Structural business statistics)
- Database – Science and technology. (n.d.). Eurostat. (see here: Science, technology and innovation)

Austria (for country-specific information see page 42)

Belgium (for country-specific information see page 45)

Cyprus (for country-specific information see page 48)

Hungary (for country-specific information see page 50)

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Portugal (for country-specific information see page 68)

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Slovenia (for country-specific information see page 74)

Spain (for country-specific information see page 77)

Switzerland (for country-specific information see page 80)

Economic Potential from Increased Labour Market Participation and Voluntary Activity

Definition:
Quantification and economic evaluation of increased labor market participation or voluntary activity due to an AAL product or service (own development).

Source of data:
Statistical offices, voluntary organizations, volunteer agencies/exchanges, and reactive surveys among employees and volunteer helpers.

Non-independent workers or employees most essentially receive remuneration in return for the time needed to fulfill their duties. However, volunteering and voluntary commitment are considered a donation of time and are therefore unpaid (based on Klie et al. 2009:59).

Object of measurement:
The extent of employment (in hours) is recorded within the framework of the reactive data collection. For the determination of the economic potential from increased labor market participation existing and legally binding records on personnel expenses can be used.

The extent of voluntary work (in hours) is recorded within the framework of the reactive data collection and its economic potential is multiplied by available minimum hourly rates. This procedure leads to a systematic monetary underestimation of voluntary work because it can be assumed that volunteers also perform activities that could be paid at a higher rate.

Time of measurement:
Both the paid and unpaid workload should be recorded for certain time intervals (e.g. 4 weeks) and at the beginning and end of an AAL project test phase and then contrasted with the comparative results of a control group.

Measurement mode:
Data collection can be done through different modes, e.g., a paper or online questionnaire, telephone, or personal interviews with AAL users. If accessible, data could also be obtained from administrative sources (based on OECD 2018:218).

Further notes:
Regarding net monthly income (incl. pro rata holiday pay and Christmas bonus), the median value per employee should be used depending on socio-economic characteristics (e.g. age, highest completed school education, full-time/part-time, professional position, etc.) the respective field of activity. The median proves to be much more robust against outliers than the average (arithmetic mean).

Databases and cross-references to country-specific information:

European Union and EFTA

- Database - Labour Market (incl. LFS). (n.d.). Eurostat (see here: Earnings)
- Database - Purchasing power parities. (n.d.). Eurostat (see here: Purchasing power parities)
- Database - Income and living conditions. (n.d.). Eurostat (see here: Income and living conditions)

Austria (for country-specific information see page 42)

Belgium (for country-specific information see page 45)

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Hungary (for country-specific information see page 50)

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Slovenia (for country-specific information see page 74)

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4.3. Application Example Being active & Human Potential: HiStory – Sharing your stories of your heritage

Brief description of the AAL solution:[5] The HiStory project uses the concept of storytelling as a means to promote social integration, cognitive activity, and the well-being of elderly people. The project aims to create a solution that enables people to tell, share and consume personal stories, thereby creating connections through shared experience. HiStory uses existing technological components and consists of the following components:

- A mobile app for recording and saving personal stories. The app supports various media formats and allows the sharing of stories with other users as well as the retrieval of stories via the app.
- An online tool to search, edit, tag, and compile stories on different topics and for different applications such as museum exhibitions, city walks, or school lessons.

Furthermore, the collected stories can be used to create innovative services in the fields of tourism, education, and culture. In this way, HiStory contributes to the collective and active writing of history (oral history) and promotes successful aging on an individual level.
The target groups of the project are storytellers (so-called “third agers”, i.e. elderly people who are mobile and can actively participate in social life) and story consumers (people who retrieve the stories saved) as well as story mediators (people who use the stories in a specific application context). In a first step, requirements for usage are collected in interviews and co-design workshops among these target groups. Based on these requirements, a design concept is created, a system architecture is established and various apps related to the context of usage are developed. These are initially evaluated under controlled conditions in the laboratory and then in the field in two longer field tests with different target groups.

Project data:

Duration:	01 April 2019 – 31 March 2022
Funding authority:	Federal Ministry for Climate Action, Environment, Energy, Mobility, Innovation and Technology (BMK, formally known as BMVIT) European Community
Program management:	Austrian Research Promotion Agency (FFG)
Program:	ICT of the future: benefit – Opportunity through demographic change AAL Programme 11th call: Smart Solutions for Ageing Well
Project management:	Mag. Claudia Schallert

[5] Schallert, C. (2019); HiStory - Sharing your stories of your heritage; https://projekte.ffg.at/projekt/3110110

Project partners: NOUS Wissensmanagement GmbH (project management) (NOUS knowledge management GmbH)
Lucerne University of Applied Sciences and Arts – iHomeLab
AIT Austrian Institute of Technology GmbH
Nationaal Ouderenfonds
Studio Dankl
Vicino Lucerne
Ijsfontein
Municipality of Zutphen

The functions of HiStory – sharing of biographical-historical knowledge – are intended to help older people to be active, to support meaningful activities and voluntary work in the areas of tourism, education, and culture, and thus to promote well-being and social inclusion. The solution is primarily aimed at active seniors who want to create and participate. Accordingly, the solution is assigned to the 3vAALuation application area being active & human potential. Quality of life (incl. life satisfaction, self-esteem, and self-image as well as meaningful activities), social relations (social interaction and participation, ethical guidelines in technology development), and technology design (user experience, accessibility, usefulness, subjective intention of use) have been defined as key performance indicators (KPIs). In addition, stakeholder interests such as market potential, willingness to pay, and general acceptance were also included as KPIs. This multi-perspective approach as well as the large intersection of the KPIs from HiStory with the 3vAALuation indicators proves the suitability of the instruments for the project. The KPIs have not yet been defined in detail. However, this step is absolutely necessary in order to be able to examine the validity of the survey. These definitions can be formulated with reference to the operational definitions of 3vAALuation.

In the third year of the project, the HiStory prototype will be evaluated with a total of 120 study participants (40 elderly people per region). In this context, three service models are at the center of interest: with Wien Museum the cultural sector will be addressed in Austria, with Foxtrail Tourism in Switzerland and with the Dutch National Foundation for the Elderly as well as the City Council of Zutphen, the tourism and culture sector as well as the education sector will be investigated. The implementation period will be six months, with eight months in advance for the detailed development of the design and preparation of the study. Apart from the KPIs, different contexts of usage will also be compared.

As shown in Table 42, the project has a lead time (project months 1 to 12) of one year for development and conception before the field test (project months 13 to 30) and a follow-up time (project months 30 to 36) of six months for the evaluation and dissemination of the project. Depending on the respective indicator, the determination of the same takes place in the field test phase, the lead time, or the follow-up time, as shown in Table 42. The following paragraphs provide more detailed information on the specific indicator.

Within the framework of the realization of HiStory, **investment, installation and de-installation costs** arise from the implementation of the application, which are usually one-off costs

incurred during the project's initial phase. These include, for example, the programming of the application (investment; project months 1 to 12) and the installation (set-up and training; project months 13 to 15). At the end of the field test, any de-installation costs should also be taken into account (e.g. dismantling and removal; from project month 28 to 30). **Human assistance costs** (for training, support, and services for end-users) as well as expenses for **operating materials and maintenance costs** (technical operating costs (e.g. electricity), maintenance services for software updates, etc.) represent running costs that need to be paid and recorded at regular or irregular intervals (project months 13 to 30).

All expenditures for tangible investments (software, operating materials (e.g. electricity), etc.) are recorded at the purchase prices of the respective point in time (invoice date) without taking into account the deductible percentage of VAT and similar taxes. Installation, de-installation, and maintenance are mainly personnel/labor-intensive services, which is why the number of hours required per household and the hourly rate paid to employees (including any overhead costs) are documented by the implementing institution. Any personnel costs that directly contribute to the research and (further) development of the AAL solution to be evaluated must be distinguished from the personnel costs incurred. These must be added separately to the personnel costs of the ongoing R&D expenses, which could prove difficult in daily project life. Alternatively, it should be considered to deduct the personnel costs incurred for installation, maintenance, etc. from the total personnel costs and allocate the resulting difference to the **personnel costs for research & development** (within the framework of the indicator "costs and revenues during development and market launch"). Personnel costs are recorded over the entire period of the project (project months 1 to 36).

Table 42: Proposal for the temporal determination of the parameter collection in HiStory

Project month	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**	**21**	**22**	**23**	**24**	**25**	**26**	**27**	**28**	**29**	**30**	**31**	**32**	**33**	**34**	**35**	**36**
Evaluation phase:	**Lead time**												**Field phase**																		**Follow-up time**					
Investment costs	■	■	■	■	■	■	■	■	■	■	■	■																								
Installation costs													■	■	■																						
De-installation costs																												■	■	■						
Human assistance costs													■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■						
Operating materials and maintenance costs													■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■						
Personnel costs (Costs and revenues during development & market launch)	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■
Consideration of ethical guidelines	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■
Active/passive usage													■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■						
Error data							■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■						
Market potential	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■
Economic potential from increased labor market participation and voluntary activity													■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■						

Source: own representation

The **consideration of ethical guidelines** must already be taken into account when writing the project application and during the entire project period. That requires, especially in the initial phase (project months 1 to 14), the targeted information of potential participants. This includes information about project goals, potential benefits, duration of the laboratory test, duration of the field test, time schedule, planned qualitative and/or quantitative surveys, voluntary participation, and possibilities to opt-out of the project. Confirmation of the explicit information on the applicable framework conditions is made in writing by signing the informed consent before project testing in the households. This informed consent must be guaranteed and communicated throughout the entire duration.
The determination of the **health status** is not planned in this project as no direct effects of the app on health are intended.
Active usage of the AAL components in the HiStory project is defined as when participants use the apps, for example, to record a personal story, listen to a story, or when posts are sent. The app can run passively in the background during a city walk and notify story consumers when a new story is available at that location. Usage data is collected in an automatized way through logging.
The project team tests system functions in a laboratory setting with test persons and analyses occurring (subjective and objective) **error data** before the field test (project months 7 to 12). After the field test, the AAL solution runs in regular operation. Any errors that occur can be logged, analyzed and, if possible, removed.
The **financial burden for end-users** depends on the implementation of the AAL solution. The research project enables an approximate calculation of the costs for primary/secondary/tertiary users in case of a market introduction. If possible, the end users' marginal willingness to pay shall be collected in order to be able to draw conclusions about other indicators.
The **market potential** should be determined in the last year of the project (project months 25 to 36) since it can be assumed that the first results of the acceptance analyses of HiStory will be already available by then. Such analyses make it possible to revise the system if necessary, i.e., reduce or expand it by certain functions to advance the market maturity. The market volume can be estimated by linking the willingness to pay with socio-economic data (e.g. purchasing power).

With regard to the determination of the **economic potential from increased labor market participation and voluntary activity**, the extent of the voluntary work of elderly people in the respective areas can be estimated during the field test phase (project months 13 to 30). In this regard, the hours worked (e.g. per week) are documented within the framework of the questionnaire survey and linked with data from official statistics. The combination of the reactive data collection with the non-reactive measuring instruments thus makes it possible to determine the economic potential of voluntary activity. An effect on labor market participation is not to be expected as it is assumed that the participants are exclusively pensioners.

For the indicators to be collected reactively, it is proposed to use the questionnaire for the area being active & human potential. This questionnaire contains items on:

- Subjectively relevant activity level
- Autonomy & self-determination
- Life satisfaction
- Age(ing)-related self-image
- Subjective state of health
- Health control & competence
- Social interaction
- Social participation
- Digital Inclusion
- Willingness to pay
- Subjective intention of use
- Pragmatic user experience
- Stigma-free design
- Hedonic user experience
- Freedom of choice regarding service access
- Privacy
- Voluntary work

As HiStory is an unpaid activity, it is recommended to remove all items of the scale paid activity. With regard to the items on health-promoting behavior (e.g. “I consciously take actions that promote my health (e.g. sports or healthy eating)”), which HiStory does not aim at, since well-being and thus indirectly also health is to be strengthened through social interaction and participation, it can be considered to omit these as well in the case of using additional questionnaires and in the case of a potential overload of test persons due to too many items. Nevertheless, if possible, we recommend using the entire questionnaire because the available evidence for the interpretation of measured values (see Part A) refers to the entire instrument at hand.

Since a control group is not planned in research design and effects develop over time, especially in the area of social inclusion, we recommend using the questionnaire several times. As in the other examples, one or more surveys should take place before the introduction of the solution in order to determine the initial value. In the case of several surveys, the mean values should be used for the statistical analysis. In order to minimize the stress for the respondents induced by the completion of questionnaires, we recommend that these are submitted after one, three, and six months. In this way, the starting point can be compared with the endpoint (e.g. by means of a t-test for dependent samples or Wilcoxon test) or correlations can be observed over time. Furthermore, it also makes sense to compare the central tendencies of the different groups or application contexts (tourism, education, and culture).

Since the user group of HiStory is a more technology-savvy group, it can be considered to issue the questionnaires digitally. In this way, the first statistical analyses can already be calculated during the field phase. As already mentioned in connection with the other application examples, it is advisable to maintain the same survey mode (e.g. online survey, paper questionnaires) for all participants and at all points in time to keep the effects of these constant.

PART C – Cross-national Evaluations

Part C performs a benchmarking of four selected countries, focusing on demographics, infrastructure (in terms of broadband internet access), research cooperation (with Austria), design of the health and care system, as well as formal and informal care.

According to recent population forecasts, the share of people age 65 years or above but also urbanization is rising. In this context, Ambient or Active Assisted Living (AAL) products and services are intended to contribute to the increase or maintenance of the quality of life of older and aging people so that they can lead an autonomous and self-determined life for as long as possible, though at some point, there will be a need for care services.

However, countries, provinces, regions (e.g. urban and rural), or even cultures sometimes differ considerably regarding the share of formal and informal care. Benchmarking will also provide an overview concerning the supply situation of formal and informal care, and will also analyze the different funding structures and areas of responsibility (e.g., national, federal, municipal), as well as discuss which application areas are most relevant for each country. By following this approach, the operationalization of relevant key figures and indicators - depending on the respective nation – is carried out step by step and the basis for the further analysis created.

In a final step, the exemplary evaluation of selected monetized non-reactive measurement instruments according to the respective characteristics of the four countries was carried out. This approach follows the objective to show based on a specific technical solution enabling a prolonged autonomous life at home, which different framework conditions in the respective countries influence the (financing) decision for the area-wide implementation of an AAL solution, whether there are different needs due to the health and care systems, and which (economic and social) obstacles have to be overcome in the respective countries.

1. *Selection Criteria and Selection Process*

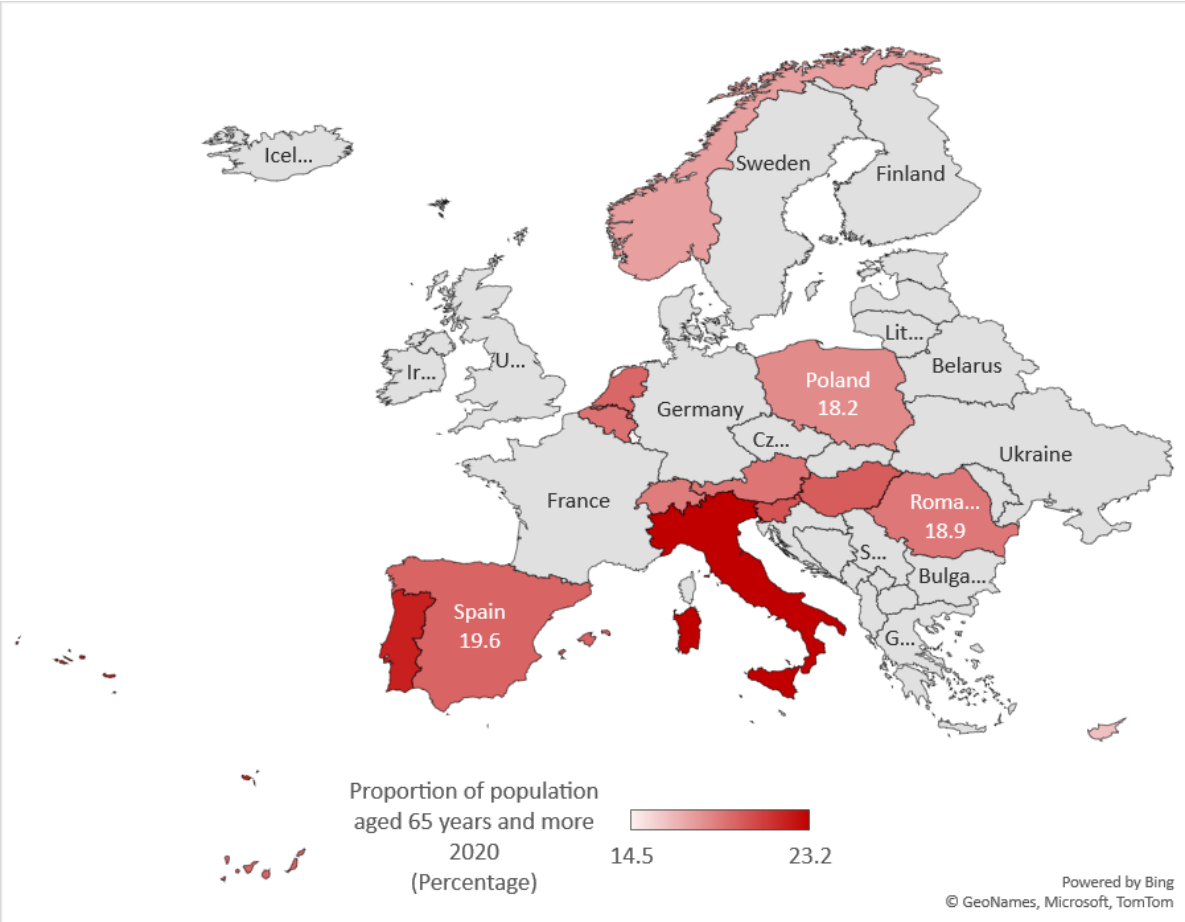
As part of the comprehensive exemplary evaluation, four of the fourteen countries of the European AAL Programme were chosen. The main criteria selected were demographics, international research cooperation (with Austria within the AAL Programme), and (broadband) Internet access. Another secondary criterion was the type of public health and care (e.g., Bismarck, Beveridge, hybrid of Beveridge and Bismarck); this was identified as an essential criterion when implementing new health technologies. The (pre)selection of the countries depends on the highest match of selection criteria:

- Demographics: mix of "young" and "old" countries (defined by the share of population aged 65 years and more)
- Research cooperation: focus on intensive cooperation with Austria (defined by the number of collaborative projects within the AAL Programme)

- (Broadband) Internet access: consideration of excellent and improvable infrastructural conditions in the member states (defined by the percentage of households with broadband access)
- Design of the welfare state according to the Beveridge (predominantly tax-funded for the entire population), Bismarck model (predominantly insured-funded for the insured population) or hybrid of Beveridge and Bismarck

The main criteria mentioned above are described below, also presenting current countries' figures.

Figure 4: Population aged 65 years and more, European AAL Programme Countries 2020, 2020



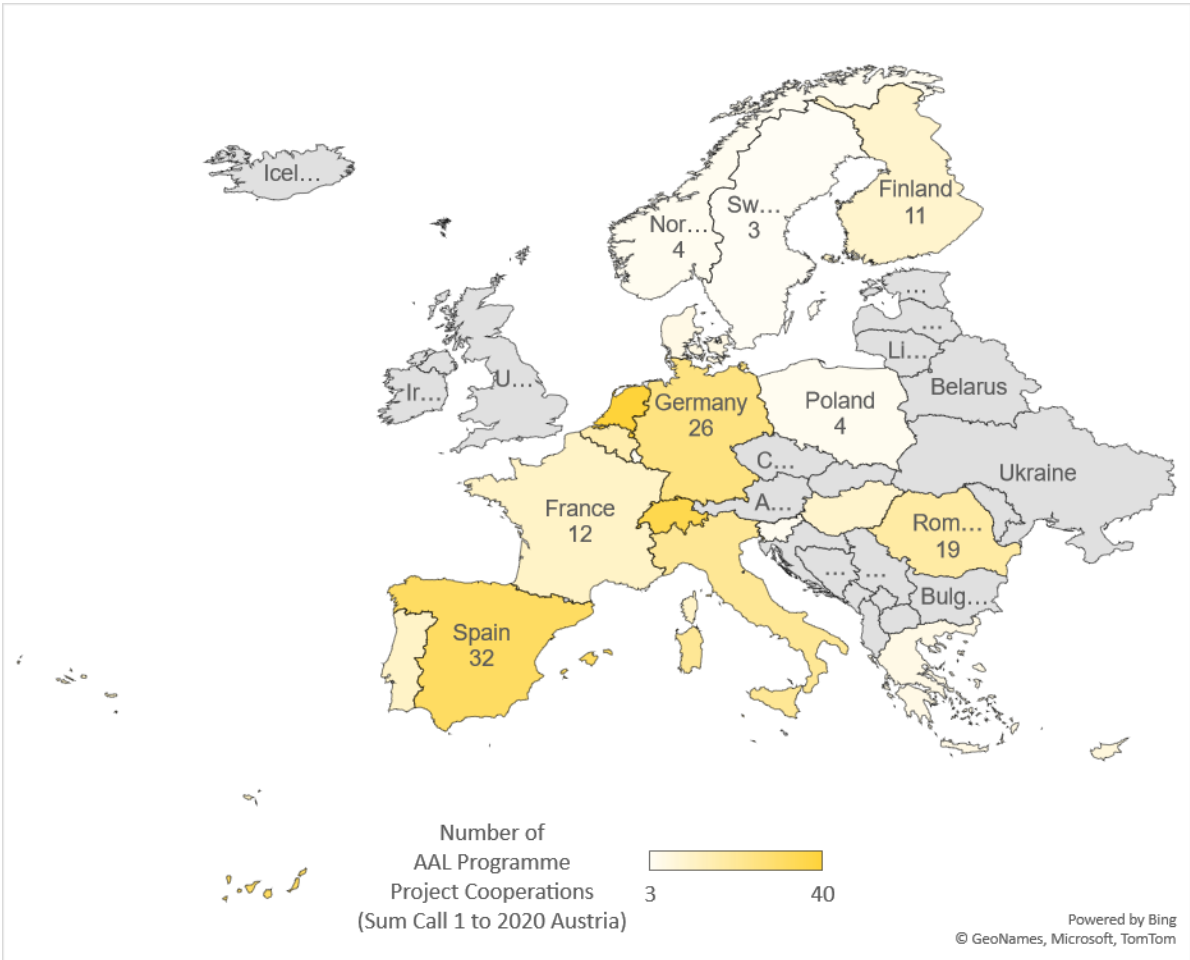
Source: Eurostat (2021c), own calculations and illustration

The increasing aging of society is creating new challenges. Particularly in industrialized countries, the proportion of people over 64 years in the total population continues to rise. This is not only putting pressure on state healthcare and pension systems. The requirements for individual care, care facilities as well as products and technologies specially developed for older people or adapted to their needs are also gaining in importance. As shown in Figure 4 southern countries of Italy (23 %), Portugal (22 %) and Spain (20 %) have the largest cohort of people aged 65 or over across Europe (European AAL Programme countries 2020). Hungary, the Netherlands and Slovenia follow with around 20 % each. The population aged 65 and over accounts

for a correspondingly small proportion of the total population in Luxembourg (15 %), Cyprus (16 %) and Poland (18 %).

Research collaborations with regional, national and international partners in science and the business community strengthen and expand scientific expertise and the research spectrum in the field of Active & Assisted Living (AAL). The integration into international networks and alliances promotes cooperation and international visibility and strengthens Austria's competitiveness when applying for large collaborative projects. In this context, Austria's international project cooperation within the framework of the AAL Programme is the focus of this analysis. In total, Austria has participated in 100 projects since the beginning of the AAL Programme (Call 1) until 2020 (Call 2020) (as of May 2021). In terms of the number of collaborative projects, the most intensive partnerships are with the Netherlands (40 collaborative projects), Switzerland (36), Italy (22), Romania (19) and Belgium (17; see Figure 5).

Figure 5: Collaborative projects with Austria, European AAL Programme Countries, Call 1 to 2020

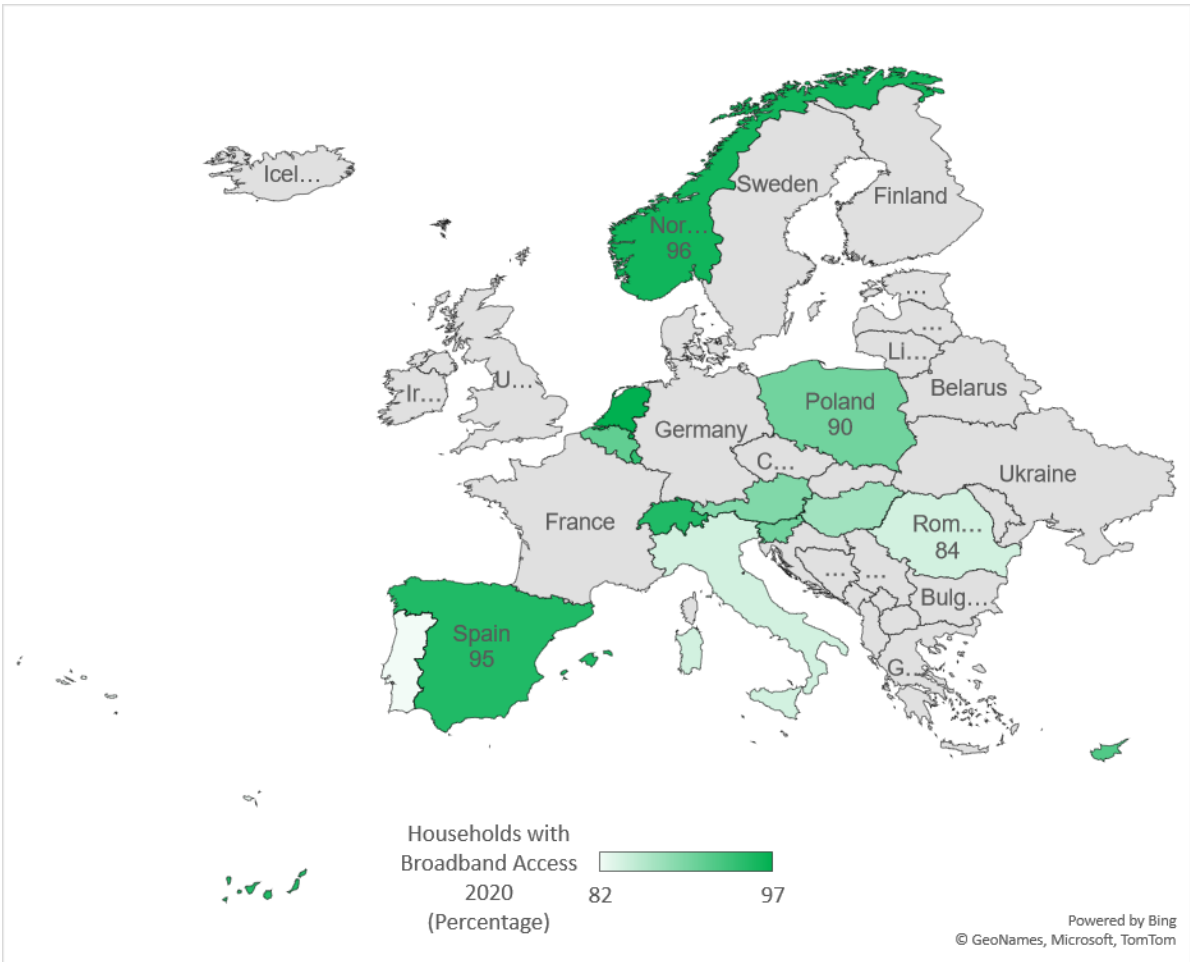


Source: AAL Programme (2021), own calculations and illustration

Broadband networks and Internet access form their foundation for economic, social and cultural activities and provide a basis for the digital transformation. Information and communications technologies (ICT) permeate all areas of life and the economy as a cross-cutting issue. The use of ICT for innovative services is intended to meet social challenges such as demographic change in both a national and international context. The Netherlands (97 %), Norway

(96 %), Spain (95 %) and Switzerland (95 %) rank at the top in regard to broadband access whereas Italy (84 %), Romania (84 %) and Portugal (82 %) need to catch up (see Figure 6).

Figure 6: Households with Broadband Access, European AAL Programme Countries 2020, 2020



Source: Eurostat (2021d), own calculations and illustration

Depending on the selection criteria and the respective characteristics, the project team of CUAS and AIT made a pre-selection of the countries to be analysed. 7 out of 13 countries (excluding Austria) met at least two out of three criteria, i.e., Italy, Netherlands, Norway, Portugal, Romania, Spain and Switzerland. In a consecutive step, four of these countries were to be identified for closer analysis. For this reason, the pros and cons of each nation were discussed and weighed against each other. These arguments were collected and tabulated, so that on May 12, 2021 a group discussion with the clients Dr.in Gerda Geyer (representing the Austrian Research Promotion Agency (FFG)) and Dipl.-Phys. in Kerstin Zimmermann (representing the Federal Ministry for Climate Protection, Environment, Energy, Mobility, Innovation and Technology (BMK)) took place. The final selection included Italy, the Netherlands, Romania and Switzerland. The high level of cooperation in research projects, the poor internet coverage, the population structure and the location in the south are crucial for Italy; because Portugal and Spain have strong similarities in this respect, they are not part of the further analysis. The high level of cooperation and the good internet access are relevant for the choice of the Netherlands; Romania was also selected because of its high level of cooperation, but the poor

internet access is of particular interest here. Switzerland is preferred to Norway because it also has a high level of cooperation and, together with Germany and Austria, is a german-speaking country. Upon this, the selection of countries represents a large variability (see Table 43).

Table 43: Selection process, European AAL Programme Countries 2020, 2020

Criteria/ Country	Research Cooperation (Call 1 to 2020)	Broadband Access (Percentage 2020)	65 years and more (Percentage 2020)	Final selection: Pros	Final selection; Cons	Healthcare System
Austria	100	89	19			Bismarck
Belgium	17	91	19			Bismarck
Cyprus	8	92	16			Bismarck
Hungary	11	87	20			Bismarck
Italy	22	84	23	high cooperation; poor internet coverage; oldest population, Beveridge-Bismarck	ES/IT/PT as southern countries; ES/IT with Beveridge-Bismarck model (?)	Beveridge-Bismarck
Luxembourg	4	94	15			Bismarck
Netherlands	40	97	20	high cooperation; good internet coverage		Bismarck
Norway	4	96	18	northern country; young population; Beveridge	Low cooperation; EFTA (?)	Beveridge
Poland	4	90	18			Bismarck
Portugal	12	82	22	poor internet coverage; Beveridge	ES/IT/PT as southern countries; medium cooperation	Beveridge
Romania	19	84	19	high cooperation; eastern country; poor internet coverage		Bismarck
Slovenia	4	90	20			Bismarck
Spain	32	95	20	high cooperation; good internet coverage; Beveridge-Bismarck	ES/IT/PT as southern countries; ES/IT with Beveridge-Bismarck model (?)	Beveridge-Bismarck
Switzerland	36	95	19	high cooperation; D/A/CH region		Bismarck

Source: AAL Programme (2021), Eurostat (2021c), Eurostat (2021d) own calculations and illustration

2. In-depth country comparison

For the selected countries, an in-depth analysis of the health and care system was carried out in a subsequent step, and reference was made to the design of the respective system. This analysis reveals differences in organization and funding in the respective states, which have to be considered in the practical implementation of AAL.

Italy

In 2019, healthcare is predominantly financed through government schemes (73.8 %), and compulsory contributory health care financing schemes only account for 0.2 %), with an additional 23.3 % from out-of-pocket payments (OOP). Most public funding comes from government spending, while the contribution of voluntary health insurance (VHI) is 2.8 % (Eurostat 2021b).

The central government plays a steering role, setting the basic principles and objectives of the health system and defining the basic package of health services available to all citizens, while the regions are responsible for organizing and providing primary, secondary, and tertiary health services, as well as preventive and health promotion services (Ferré et al. 2014; Poscia et al. 2018).

Organization, Structure and Provision of Regional Public Health and Care Services

At the national level, primary responsibility for public health lies with the Ministry of Health, supported by the National Health Council. The council operates an executive committee, a general assembly, and five departments dealing with various health and social issues. Its distributed activities are organized by seven departments, eight national reference centers, and seven centers collaborating with the World Health Organization (WHO). In addition, the Italian Medicines Agency coordinates activities at the national level concerning medicines and promotes investment in research and development, monitors access to drugs and their safe and appropriate use and promotes knowledge about medication and the collection and evaluation of international best practices. The National Centre for Disease Prevention and Control and the National Agency for Regional Health Services also have essential roles in supporting national and regional levels in carrying out public health-related functions. The first one assists regional technical working groups involved in public health programmes and maintains relationships with international networks on epidemiology and public health. The latter one is in charge of supporting national and regional health planning, comparing the costs and efficiency of health care services, detecting problems in managing health resources, and disseminating innovative approaches (Ferré et al. 2014; OECD/European Observatory on Health Systems and Policies 2019; Poscia et al. 2018). Implementation of health policies takes place at a regional level. Local health units (LHUs) are responsible for organizing and providing health and

care services such as preventive medicine, public health services, primary care services including family medicine and community services, and secondary care. LHUs further split up into districts regulating public health and primary care services. Inpatient care is provided through a network of publicly- and privately-owned hospitals, with general practitioners and pediatricians playing a gatekeeping role (Ferré et al. 2014; OECD/European Observatory on Health Systems and Policies 2019; Poscia et al. 2018).

Financing

In 2019, healthcare is predominantly financed through government schemes (73.8 %) and compulsory contributory health care financing schemes only account for 0.2 %), with an additional 23.3 % from out-of-pocket payments (OOP). Most public funding comes from government spending, while the contribution of voluntary health insurance (VHI) is 2.8 % (Eurostat 2021b). Although most funding is pooled at the national level and redistributed to regions, there is scope for significant regional variation in tax rates (particularly through taxing corporations and a regional surcharge on income tax; Ferré et al. 2014; OECD/European Observatory on Health Systems and Policies 2019; Poscia et al. 2018).

Health and care services are delivered mainly by public providers, with some private or private-public entities. In general, doctors employed by the NHS are salaried and have civil servant status, although general practitioners and pediatricians are independent professionals, paid via a combination of capitation and fee-for-services for some interventions. In addition, all salaried doctors are allowed to practice privately and can earn additional income on a fee-for-service basis.

Payment rates for hospital and outpatient care are set by each region, with national rates (set by the Ministry of Health) serving as a guideline. Payment for hospital care (both inpatient and outpatient treatments) is based on diagnose-related group (DRG) tariffs, though this is usually supplemented with other payment methods (lump sum or global budget), whereas outpatient care is reimbursed using a tariff per unit of care. As a result, there are significant inter-regional variations in each region's prospective payment system, such as how fees are set, which services are included, and the tools used to influence care patterns (Ferré et al. 2014; OECD/European Observatory on Health Systems and Policies 2019; Poscia et al. 2018).

Physical and human resources

In 2019, Italy had 316.28 hospital beds per hundred thousand inhabitants; 82.1% of which are dedicated to curative care, 13.4 % to rehabilitative care and 4.4 % to long-term care beds (in hospitals; Eurostat 2021e).

In 2019, with 405.07 medical doctors per hundred thousand people, Italy is above the Netherlands (371.51) and Romania (318.67) but below Switzerland (434.97). The number of nurses,

midwives, health care assistants and home-based personal care workers per hundred thousand inhabitants is 1,687.77, making a ratio to medical doctors of 4.2 (Eurostat 2021f; Eurostat 2021g). Regarding health worker mobility, Italy is primarily a destination country, with higher levels of inflows for specific categories of health professionals such as nurses and care assistants (both legal and illegal), owing to chronic nursing shortages that have shifted focus to recruitment from abroad. In contrast, medical doctors are disproportionately affected by emigration (Ferré et al. 2014).

The government promotes eHealth initiatives, and current efforts aim to expand online services, electronic health records (EHRs), and the digitization of medical prescriptions and certificates. The Digital Health Agreement was signed in 2016 to manage and promote the spread of eHealth across the country in a coordinated manner. Aside from EHRs, telemedicine systems and ICT innovations to improve patient workflow management and experience are top priorities. The Strategy for Digital Growth and Triennial Plan for Public Administration Informatics 2019-2021 was developed to guide the public health system's digitalization. This Triennial Plan includes initiatives that will promote the regional implementation of EMRs, ePrescriptions, and telemedicine (OECD/European Observatory on Health Systems and Policies 2019; Poscia et al. 2018).

Long-term Care

The suppliers of LTC services are publicly or privately organized. The private sector is getting more important in Italy as 65 % of nursing homes are private. Home care services are also partly covered by private LTC suppliers and are increasing. Although there is hardly any data available, records show only 6.6 % of the over 65-aged Italians received private home care in 2008. The carers in the private LTC sector are mainly migrant workers, and work contracts are on an individual basis. About 700,000 migrant workers were employed for the home-care services for elderly people in 2008 (European Commission 2019a:394ff). It is reported that Italy has one of the highest rates of migrant workers for LTC services at home and that they are having irregular contracts (a grey market is noted). Often the households hire migrant workers who get paid by the family, also via the cash care allowance, which the dependent person receives (Jessoula et al. 2018:7ff).

In Italy, the attendance allowance is a cash allowance program for people with severe disabilities, run by the National Institute of Social Security and financed through general taxes. The program (the access and the amount of the social transfer) is not means-tested, and also a reason for the spending is not given (European Commission 2019a:394ff, Jessoula et al. 2018:7ff). Means-testings will be done to define the number of economic resources of the households getting LTC services (European Commission, 2019a:394ff).

The dependent person receives a cash allowance of approx. € 500 per month depending on the level of disability, meaning the disease (e.g., higher cash allowance for blind or deaf-mute people). The criteria of access to the cash benefit differ through the country, as well as the

criteria to access the care service. A multidisciplinary team (including medical doctors, nurses, social workers, and administrative employees) classifies the needs for the LTC services (sometimes into categories), adjusts a care plan, and chooses the LTC providers (European Commission, 2019:394ff). Families and neighbors are important stakeholders when planning and providing long-term care; especially informal care is of high relevance in Italy (European Commission, 2019:394ff). A cash allowance of approx. € 500 is not sufficient in many cases to have access to formal LTC. For this reason, lower-income households hire informal care workers and pay the salary (respectively the cash allowance) to the migrant workers. But mostly only if the household has an additional income (Jessoula et al. 2018:7ff). The culture of care is different between the northern and the southern part of Italy. Up in the North, formal LTC services are more common; this might be due to an increased labor force participation rate of women. Home care facilities in the northern part are well established. In the southern part, care is mainly done by family members, and only poor public (formal) support occurs (European Commission 2019a:394ff).

Public investment in residential care homes is relatively low. This leads to tensions as severe cases (e.g., last stage of dementia) that should be treated in care home facilities might be left at home. The investment in-home care is on average in comparison to other countries (European Commission 2019a:394ff).

Netherlands

Public health is considered a shared responsibility of the national government, local government (municipalities), and the private sector. The Public Health Act was enforced in 2008, and the succeeding Collective Public Health Prevention Act (1989) provides the institutional framework. Municipalities are obliged to establish and maintain a local public health service cooperating with other municipalities to organize such services. In line with the shared responsibility of the public and private sector, various public-private partnerships (PPPs) have also been set up (Kroneman et al. 2016; Maarse et al. 2018).

Organization, Structure and Provision of Regional Public Health and Care Services

The national government has the overall responsibility (regulation, funding, supervision, international collaboration, etc.), whereas municipalities manage the operative implementation of public health and care services. Besides the governmental collaboration, a cross-sectoral approach between public and private sectors is also applied as policy decisions are the result of collective decision-making (together with private industries, schools, employers, sports organizations, etc.), though the international level is also of relevance, especially in regard to global challenges as viruses, food safety (Kroneman et al. 2016; Maarse et al. 2018).

Each municipality is responsible for the following tasks: youth health care, environmental health, socio-medical counseling, regular sanitary inspections, health facilities for asylum seekers, screening, epidemiological research, health education, and mental health. Another issue is to develop and implement a local health plan. The degree of local government policy discretion in public health varies. Local governments have limited policy discretion for the more medically focused tasks, including infectious disease control, environmental public health, screening programs, and adolescent health care. For the remaining responsibilities, municipalities have wider options, and although they must consider some policy constraints imposed by the national government, they are free to decide how to transform the national public health plan into a local public health program and how to establish their local public health service (Kroneman et al. 2016; Maarse et al. 2018).

Because many municipalities are too small for their own medical agency, about 25 local services have been set up serving approx. 400 municipalities advising them on respective issues. Regional public health services focus on specific vulnerable groups, such as children and elderly persons. Municipalities are free to contract out these activities to private organizations. The public health service has a clearly defined role and expertise in the area of its medically oriented tasks, such as the control of infectious diseases. Other areas of intense collaboration between the public health service and municipal agencies are the management of large-scale incidents and policy areas where effective public health action requires an intersectoral approach (e.g. in the care for older people, addressing over-weight and obesity, promoting physical activity or addressing mental health problems; (Kroneman et al. 2016; Maarse et al. 2018).

General practitioners (GPs) or other primary care practitioners (e.g., midwives, dentists) act as gatekeepers in the Dutch system, meaning hospital and specialist services require a specific referral. Approx. 93 % of all consultations are handled within primary care, and therefore, only 7 % result in referrals to secondary care. After receiving a referral, patients can choose which hospital they want to be treated, but reimbursement may depend on the type of health policy. Benefits-in-kind policies are unlikely to reimburse full costs for care from a provider who does not have a contract with that insurer; reimbursement policies enable freer choice and refund all 'reasonable' costs (Kroneman et al. 2016; Maarse et al. 2018).

For access to residential care, an official assessment is obligatory. Corresponding patients can choose between receiving care in a residential home or at their own home. The district nurse assesses and coordinates long-term care at home for patients who do not need 24-hour supervision. Assessments of needs for domestic care and social support are mainly carried out by employees of the municipality or social district teams that are coordinated by municipalities. Although recent reforms envisage a more central role for informal carers in caring for the sick and disabled, financial compensation and facilities for carers are limited and have recently been reduced (Kroneman et al. 2016; Maarse et al. 2018).

Financing

In 2019, healthcare is predominantly financed through compulsory contributory health care financing schemes (76.2 %) and government schemes (6.5 %), with an additional 10.6 % from out-of-pocket payments (OOP). Most public funding comes from the social health insurance schemes, while the contribution of voluntary health insurance (VHI) is 6.8 % (Eurostat 2021b).

Adults pay a community-rated premium to their insurer (the government pays the premium for children), plus an income-dependent premium into a central fund, risk-adjusted redistributed among insurers.

General practitioners (GPs), maternity care, hospital care, home nursing care, pharmaceutical care, and mental healthcare are all included in the basic benefits package. However, except for GP consultations, maternity care, home nursing care, and care for children under 18, the first € 385 (in 2019) must be paid out of pocket (Kroneman et al. 2016). Services not covered by the basic package can be insured through voluntary health insurance (VHI) (accounting for 6.8 % of financing in 2019; Eurostat 2021b). Price and quality of care are negotiated by health insurers and providers. A national healthcare authority sets maximum prices for care for which negotiation is not possible, such as emergency care or organ transplantation. Healthcare providers are self-employed, non-profit business owners. Diagnosis Treatment Combinations is an adapted diagnosis-related group (DRG) system used to pay hospitals. General practitioners are compensated through a combination of fee-for-service, capitation, bundled payments for integrated care, and pay-for-performance (focused on issues such as accessibility and referral patterns).

Apart from home nursing (which falls under healthcare) and residential long-term care (which is funded through a specific scheme funded by an income-related levy), municipalities are primarily responsible for long-term care (Kroneman et al. 2016; Maarse et al. 2018).

Physical and human resources

In 2019, the Netherlands had 307.84 hospital beds per hundred thousand inhabitants, 85.0 % of which are dedicated to curative care, 3.4 % to rehabilitative care, and 11.6 % to long-term care beds (in hospitals; Eurostat 2021e). The long-term care sector is seeing a steady reduction in bed supply and an increasing overlap of functions between nursing homes (providing nursing and rehabilitation care) and residential homes (for people who cannot live at home; Kroneman et al. 2016).

With 371.51 medical doctors per hundred thousand people, it ranks below Switzerland (434.97) and Italy (405.07) but above Romania (318.67). The number of nurses, midwives, health care assistants, and home-based personal care workers per hundred thousand inhabitants is 2,441.71, making a ratio to medical doctors of 6.6 (Eurostat 2021f; Eurostat 2021g). The traditional work settings and division of labor between medical professions have changed over the years. Professionals in primary care increasingly work in larger organizational settings (such as primary healthcare centers), supported by allied staff and managers, and work in multidisciplinary teams. Community pharmacists increasingly work in structured collaboration with GPs in their catchment area. Some tasks are being transferred from doctors to nurses. As a result, new occupations exist, such as practice nurses, nurse practitioners, nurse specialists (who can also prescribe medicines in an ongoing pilot), and physician assistants. Furthermore, there is a focus on shifting care from secondary care to primary care, mainly for chronic diseases and for simple, low-risk treatments, such as minor surgery (Kroneman et al. 2016; Maarse et al. 2018).

Long-term care

The Netherlands implemented LTC insurance in 1968. This insurance covers home care and institutional care of elderly people and people with mental and physical disabilities. Important to mention is that a cost-sharing through the income existed for all LTC services. Especially for residential care, a contribution has to be paid for the service package, including food, lodging, and care. In 2016 the expenditure on residential care facilities was very high (92.7 % compared to the EU-average 56 %). By that, an inefficient use was reported, as well as the GDP per capita was at 185, which is more than double of the EU average (77.1 per capita in 2016). In 2016 the expenditure for LTC at home was only 7.3 % of the total LTC budget. The LTC-insurance “Exceptional Medical Expenses Act” is now replaced by other acts because the number of covered benefits was too high. In 2016 the Netherlands spent € 1.3 out of € 19.9 billion of the whole budget, whereas € 1.3 billion were attributed to the personal budget (6.5 % of total expenditure for the LTC-Act).

The LTC-Act is installed, especially for people with high needs of care, and is funded by a premium through the income with a ceiling of € 33,589 and a co-payment regulation for adults. Additional facts like age (over 65), the care service (living at home or not), and marital status are considered. The Social Support Act covers the services of personal care in nursing homes and care at home, but only for people that need little help.

Most clients apply for care-in-kind, but since the mid-90s, they may also choose financial support to purchase private services (personal budget). There is a strong demand for cash allowances, but experts reported that the in-kind benefits have not declined yet and that informal care will also tend to be displaced. The personal budget may also be used for informal care (European Commission 2019b). So, they may receive direct and indirect financial support, and the cash receiver is also the user of care service (Zigante 2018:24ff).

The eligibility criteria for receiving support from the LTC-Act is assessed by the Care Assessment Center. Important to mention that this assessment is for cash benefits and benefits-in-kind and measures the needs and characteristics of the clients within a standardized system. The Care Assessment Center decides what kind and how much support the client needs, and then the client can choose either getting in-kind care (in a nursing home or at home) or a cash benefit (early mentioned personal budget). The personal budget is roughly the same amount as the care-related costs of residential care. The clients have to prove that they spend the money on care services.

The services under the Social Support Act are distinguished between general provisions and personalized provisions. The general provisions focus on community activities such as transport or recreational activities. The personalized provisions focus on the individual and include domestic assistance and support. The assistance services aim to provide an independent lifestyle and, for example, give support in organizing the household. The Dutch government encourages municipalities and social housing associations as well as care institutions to build homes that are adapted to the needs of the elderly, and also access to local care provides a long independent living. So, they aim to support independent living also by providing effective care at home, telecare, and improving accessibility living.
Under the Social Support Act, the local authorities are in charge of the care services for the clients, who may request their need and will then be supported by the local authorities or by the GP to receive in-kind care or the cash benefits (European Commission 2019a:428ff, European Commission 2019b).

Noteworthy is that the LTC reform in 2015 fragmented the Dutch system more and more. Due to a lack of quality in nursing homes, the Dutch aimed to postpone the care services to home care. Hereby a lack of coordination skimping on quality occurred. But to be able to move into a nursing home, the dependent person is only qualified when he/she needs 24 hours supervision. This results in people with a significant care burden living at home, and the pressure on the informal care systems increases (OECD 2019b:19).

Romania

The Romanian health and care system is a highly centralized social health insurance (SHI) system providing a comprehensive benefits package to 89 % (2017) of the population. The remaining 11 % have access to a minimum package of benefits (OECD/European Observatory on Health Systems and Policies 2019).

Health and care provision is characterized by underprovision of primary care and inappropriate use of inpatient and outpatient services mainly attributed to high rates of emigration to wealthier European countries in the past (OECD/European Observatory on Health Systems and Policies 2019; Vladescu et al. 2016).

Organization, Structure and Provision of Regional Public Health and Care Services

Health and care system organizes on a national and a district-level mirroring Romania's administrative division. The central government sets general objectives while districts ensure service provision according to the rules set from the national level (centralization). The Ministry of Health is the main administrative authority for health and care issues monitoring and setting its regulatory framework represented by district public health authorities on a local level. The National Health Insurance House administers and regulates the social health insurance system (SHI), also having district representatives (Vladescu et al. 2016).

Primary care, primarily done by general practitioners (GPs), acts as a gatekeeper, although direct access to a specialist is possible for specific conditions. Primary health care services remain underused, and hospital services are overutilized. There are inequities in access to primary care, with access poorer in rural areas. Specialized ambulatory care is provided through a network of hospital outpatient departments and polyclinics, specialized medical centers, centers for diagnosis and treatment, and individual specialist physician offices under contract with the district public health authorities (Vladescu et al. 2016).

Hospitals offer inpatient care varying in size, competencies, and catchment areas. Accessibility of specialized ambulatory care and inpatient care is poorer in rural areas compared to urban areas. Daycare is provided in hospitals and health care centers under contract with the district public health authorities (Vladescu et al. 2016).

Rehabilitation care is provided in ambulatory and inpatient settings, but access to such care is not adequate, and there are long waiting lists. Access to long-term care (LTC) and palliative care is also poor. Romania has one of the lowest residential LTC coverage rates in Europe, with only 7.9% of the needs for palliative care covered in 2014. Mental health care is still largely provided in institutional settings, and a shift to community settings has yet to be achieved (Vladescu et al. 2016).

Financing

In 2019, healthcare is predominantly financed through government schemes and compulsory contributory health care financing schemes (80.5 %), with an additional 18.9% from out-of-pocket payments (OOP). Most public funding comes from the social health insurance schemes (65,0 %), while the contribution of voluntary health insurance (VHI) is marginal (0.4 %; Eurostat 2021b).

Though SHI is compulsory, it covers only around 89 % (2017) of the population. Uninsured groups are people working in agriculture or those not officially employed in the private sector; the self-employed or unemployed not registered for unemployment or social security benefits. Insured individuals are entitled to a comprehensive benefits package, while the uninsured are entitled to a minimum benefits package only covering cases of emergencies, epidemic-prone/infectious diseases, and care during pregnancy (Vladescu et al. 2016; OECD/European Observatory on Health Systems and Policies 2019).

Since implementing preventive national health programs, some emergency care and capital investments are funded by the Ministry of Health, while local budgets finance hospital maintenance, repairs, and inpatient meals. OOP payments consist mainly of direct payments for services offered by private providers and co-payments for drugs, up to 80% of the retail price for some expensive prescription drugs and other services. In addition, the NHIH finances DHIHs to purchase services for the insured population in their respective geographical areas (Vladescu et al. 2016).

Medical doctors on the primary level work as freelancers with their own practices receiving payments based on a mix of age-weighted capitation and fee-for-service (FFS). Outpatient ambulatory care specialists contract with the DHIHs getting paid on an FFS basis, while inpatient specialists working in hospital ambulatories receive a salary, as do other hospital physicians; the same situation applies to nurses in public and private health cares. Hospitals receive prospective payments consisting of a mix of payment methods, including a diagnosis-related groups (DRG) system. Emergency services and certain public health care services receive tax-based funding from the central government (Vladescu et al. 2016).

Physical and human resources

In 2019, Romania had 705.75 hospital beds per hundred thousand inhabitants; 75.6 % of which are dedicated to curative care, 9.6 % to rehabilitative care, and 14.9 % to long-term care beds (in hospitals; Eurostat 2021e). With 318.67 medical doctors per hundred thousand people, Romania ranks below Switzerland (434.97), Italy (405.07), and the Netherlands (371.51). The number of nurses, midwives, health care assistants, and home-based personal care workers per hundred thousand inhabitants is 1,142.28, making a ratio to medical doctors of 3.6 (Eurostat 2021f; Eurostat 2021g).

The comparatively low number of medical doctors and nursing staff relies on high rates of out-migration to other European countries. This is because of low salaries, low social status, lack of performance recognition, limited career development opportunities, and wide discrepancies between the levels of required competencies and working conditions that do not enable the skills acquired to be applied in practice (Vladescu et al. 2016).

General practitioners (GPs), outpatient care, and ambulatories have been using information and communication technologies (ICT) since the introduction of electronic reporting requirements in 1999. Hospitals have applied electronic reporting since the introduction of the diagnosis-related group (DRG) reimbursement in 2006. ePrescription was implemented in 2012, while National Health Insurance Card (2015) has been in use since 2015, containing patient identification data (Vladescu et al. 2016).

Long-Term Care

In Romania, there is no insurance for LTC. The LTC system is regulated by several laws concerning healthcare, social support, pensions, and rehabilitation. Care of the dependent elderly is primarily done by family members and neighbors, i.e. informal care. The formal care sector mainly covers only people with long-term medical care needs.

LTC is financed due to the service either by the public pension budget, the National Health Insurance Fund, by the local budget (especially the home care), or the funds from the state budget (Ministry of Labour, Family, Social Protection and Aged Persons; especially cash benefits and allowance).

There are three types of care available for elderly people defined by the law, i.e. temporary or permanent home care, temporary or permanent residential care and, daycare in residential homes. The home care includes defined services such as household services (re-socialization or prevention of social exclusion, legal and administrative advice, payment of certain household duties, catering, etc.), socio-medical services (personal hygiene, socio-cultural activities, etc.) and, Medical services (medical appointments, medicine administration, etc.).

Social Assistance Law states every dependent person is allowed to receive individual care, meaning that care services individually relay specific needs, daily activities, family status, and personal lifestyle. Long-term care lasts longer than 60 days. Older adults, disabled persons, and people suffering from chronic diseases are in favor of personal care. Sometimes personal care is combined with medical care, rehabilitation, or other recovery services. Local authorities hire nursing staff for care at home.

For disabled people, there are cash benefits and in-kind services for social and medical affairs. They may also choose whether they take temporary or permanent care. Disabled people have

to pay a monthly contribution when choosing permanent residential care. In addition, they receive two types of services: prevention of social exclusion and special care for their physical and psychical capacities. Services for older adults are almost the same.

There are no cash benefits for informal care of the elderly except for those only officially recognized as people with disabilities by the respective authorities. So, if the dependent person suffers from chronic illness or multiple comorbidities, they may be assessed as presenting a degree of disability. The dependent persons will then benefit from care allowance, which is then usually given to a family member. Caregiving spouses or relatives have the right to work part-time, while the local authorities take on the income loss (but this belongs to the local initiative). Most caregivers work informally for the dependent and get paid informally, such as family members or hired caregivers. As so far, the informal sector is hard to estimate (Pop 2018:10).

Personal care (assistance of activities of daily life) will be provided by professional care only if there are no informal or volunteer caregivers available. Concerning access to a nursing home, a number of criteria have to be met (e.g. no relatives, no income, no apartment, permanent care necessary, etc.). If the dependent person, who receives formal home care service, has a regular income (pension income), he/she has to pay a monthly contribution due to its income and type/scope of care service. Similarly, if the elderly (with regular income) chooses a nursing home, he/she has to pay a monthly contribution (European Commission 2019a:451ff, European Commission 2019c).

The Romanian state also aims to install two programs preventing the institutionalization of elderly people. Firstly, case management should be installed for supporting elderly people with social services, and secondly, the municipalities should install social assistance programs to provide social services. Furthermore, the state finances social workers for local authorities where no social service can be installed. The National Health Strategy 2014-2020 focuses on reform of several care services such as palliative care and implementing a classification for LTC due to levels and types of care (European Commission 2019a:451ff, European Commission 2019c).

Important to mention is that the European Commission (2019:398, 434, 456) notes the same challenges for the Italian, the Dutch, and the Romanian long-term care systems due to supporting family carers. They explain that they should establish policies for supporting informal carers, such as through flexible working conditions, short-term care, carer's allowance as a replacement for lost wages or coverage of care-related expenses, cash benefits for the recipient without reducing the incentives for employing carers, and women should not be encouraged to take on the care of family members and withdraw from the labor market.

Switzerland

All residents have basic mandatory health insurance (MHI), which covers a state-determined catalog of benefits that applies uniformly to all insured persons. The health care system is largely financed on a solidarity basis, with the main burden borne by private households and the public sector, although out-of-pocket payments are relatively high compared to other countries.

Organization, Structure and Provision of Regional Public Health and Care Services

In the Swiss health care system, tasks and responsibilities are distributed among the federal government, the cantons and the municipalities. The cantons have a very large power, although the role of the federal government is increasing (compulsory health insurance, quality and safety of medicines and medical devices, research and development, etc.). All residents have compulsory basic health insurance (MHI), which includes a state-determined catalog applying uniformly to all insured persons. Regulated by federal legislation, this catalog includes most primary care and specialist services, as well as inpatient care and services provided by other health care professionals (when prescribed; De Pietro et al. 2015; Angerer & Liberatore 2018).

The cantons are responsible for healthcare provision. This includes planning, controlling and co-financing the services of hospitals, clinics and long-term institutions but they are also in charge of issuing and implementing a large proportion of health-related legislation and carrying out prevention and health promotion activities. The Conference of Cantonal Health Directors supports the 26 cantons in this task by developing recommendations and principles in mutual exchange, including recommendations on hospital planning as canton share hospitals to some extent (De Pietro et al. 2015; GDK 2021).

Outpatient care is mostly provided by independent physicians in private practices who offer both primary care and specialized care. Insured have a very high degree of freedom in choosing a physician and hospital, and general practitioners (GPs) do not act as gatekeepers. Hospitals provide inpatient care though playing an increasingly important role in the provision of ambulatory and daycare services. Long-term care, rehabilitation care, palliative care and psychiatric care are also the responsibility of the cantons. However, these can delegate responsibility to the municipalities, with informal caregivers provided by relatives playing an important role (De Pietro et al. 2015; Finkenstädt 2015).

Financing

In 2019, healthcare is predominantly financed through compulsory contributory health care financing schemes (44.3 %) and government schemes (22.5 %), with an additional 25.3 % from out-of-pocket payments (OOP). Most public funding comes from the social health insurance schemes, while the contribution of voluntary health insurance (VHI) is 7.9 % (Eurostat 2021b).

Capitation payments finance compulsory health insurance, i.e. this is independent of income and can vary depending on the canton and insurer. Progressively higher premiums apply to three different age groups, with only a lower premium for children (0 to 19 years) and young adults (19 to 26 years). Mandatory health insurance (MHI) plans offer different packages that vary in the amount of deductible and the choice of provider. The minimum annual deductible is approximately €275 for adults, and the maximum deductible is about €2,300. In addition, a co-payment rate of 10% applies to all benefits. Deductibles are not covered by voluntary health insurance (VIH). MHI may be not-for-profit, but the same companies may offer VHI, which may be for-profit. Private financing is most relevant for dental care as well as outpatient and inpatient long-term care (De Pietro et al. 2015; European Commission 2019d).

Physical and Human Resources

In 2019, Switzerland had 459.34 hospital beds per hundred thousand inhabitants, 78.1 % of which are dedicated to curative care, 18.5 % to rehabilitative care, and 3.4 % to long-term care beds (in hospitals; Eurostat 2021e). With 434.97 medical doctors per hundred thousand people, Switzerland ranks top in front of Italy (405.07), the Netherlands (371.51), and Romania (318.67). The number of nurses, midwives, health care assistants, and home-based personal care workers per hundred thousand inhabitants is 2,595.33, making a ratio to medical doctors of 6.0 (Eurostat 2021f; Eurostat 2021g).

Healthcare facility owners are responsible for managing investments, and since the introduction of billing by diagnosis-related groups (DRG) in 2012, hospital investments are also financed from revenues for services. There is a high dependence on foreign-trained healthcare personnel; almost 30% of all active physicians in Switzerland have a diploma from a foreign medical university (mostly from Germany; De Pietro et al. 2015).

Long-Term Care

The Federal Statistical Office (2021) recorded that in 2017, that 13.0 % of the total population received informal care from family members. 15.6 % of men and 29.5 % of women aged over 80 years received informal care.

In Switzerland, the professional care and support service at home is called Spitex. In 2017 13.3 % of men and 20.9 % of women over 80 years received the care service from Spitex.

Spitex does not displace informal care; in fact, 59% of those cared for by Spitex receive additional informal care.

The health insurance partly covers the care services, but different criteria have to be met (criteria according to the Health Insurance Service Ordinance). All insured people pay a fixed contribution to the care services, from which the care at home or in a residential home is covered. Nevertheless, the dependent person has to cover a certain contribution for the care service (about 20 % of the service costs) and has to pay also the premium of the health insurance. The costs refer to the amount and type of service. The payment of the insurance is only for the care, and other services associated with the need of care have to be covered by the dependent person itself, such as support, home help service, and board/accommodation in residential care homes. The cantons and municipalities are involved in financing and covering the remaining costs. Access care services, the need must be ordered/precepted by a doctor, and then a nurse assesses the needs. For nursing homes, the assessment is due to the criteria of the Health Insurance Service Ordinance. In Switzerland, the types are home-care services are daycare and overnight care facilities and nursing homes.

The care can be provided according to a prescription of a doctor by registered nurses, organizations for assistance, and home-care or nursing homes. But the caregivers have to meet the appropriate authorization with regard to the qualification and the cantonal requirements in order to bill the services directly with the health insurance (Federal Office of Public Health 2021). In 2019, 2,339 organizations for home care services occurred, with 24,755 full-time workers (Federal Statistical Office 2020).

Furthermore, in 2016 32.7 % of women did not work due to family care (Trein 2018:7f). Important to mention is that there is no direct financial support, such as the cash care allowance, as in other countries, in Switzerland (Federal Office of Public Health, 2021). According to in-kind benefits, relatives may get information and training services for informal caring (Trein 2018:7f).

3. Quantitative Analysis of Formal and Informal Care, Labor Force Participation and Volunteering

According to recent population forecasts, the share of people aged 65 years or above but also urbanization is rising. In this context, Ambient or Active Assisted Living (AAL) products and services are intended to contribute to the increase or maintenance of the quality of life of older and aging people so that they can lead an autonomous and self-determined life for as long as possible, though at some point, there will be a need for care services. Therefore this section analyzes important metrics when it comes to formal and informal care of the elderly. In this context, special attention is paid to the regional design of the formal care system.

If the formal care system does not provide sufficient cash and in-kind benefits, caregivers, i.e. family members, neighbors, friends, etc., have to provide informal help. These two indicators are thus directly causally related as inadequate care provision leads to a higher proportion of informal care.

This, in turn, has many implications for other economic sectors such as the labor market. As a result of informal care, a large number of people are not available to the primary labor market or only to a limited extent. For women, in particular, this means a lower employment rate because they are more traditionally in charge of raising children and caring for relatives. In turn, this results in poorer prospects for careers and productivity losses in the long term compared to men and, in addition to economic inequality, also creates social inequality between these two population groups.

Volunteering is an interface between the above-mentioned key figures and indicators. Both younger and older age cohorts engage in volunteer associations to broaden their horizons, socialize, engage and network, make themselves useful and feel needed within a social group and/or society. From an economic and social point of view, voluntary, unpaid, and unpaid activities result in a variety of positive externalities for both the recipients and the providers: Volunteers often make an important contribution to weaker groups of people (the elderly, the sick, children, the socially disadvantaged, etc.) and thus often feel needed and remain active and integrated into society. Conversely, their unpaid work helps to relieve the budget of the federal, state and local governments, which would otherwise have to pay for these social services.

3.1. Formal Caregiving

As for the use of professional home care, the highest rate is in the Netherlands with a total number of 5.5 % of the total population and in all areas of urbanization (5.6 % in cities, 5.5 % in the suburbs, 5.4 % in rural areas). The lowest rates are in Romania, where only 0.2 % of the total population took advantage of professional care at home in 2016. As Table 44 summarizes, the total rate in Italy is around 1.2 %, only in rural areas is the rate slightly higher (1.4 %). In Switzerland, the share of professional care at home is around 2.1 %. However, in Swiss cities, the rate is higher with 2.9 %, than in rural areas with 2.4 %, and in Swiss suburbs, only 1.6 % used professional home care in 2016.

Table 44: Individuals receiving professional home care by degree of urbanization, 2016

Countries	Cities	Towns & suburbs	Rural	Total
Italy	1.2%	1.1%	1.4%	1.2%
Netherlands	5.6%	5.5%	5.4%	5.5%
Romania	0.2%	0.1%	0.2%	0.2%
Switzerland	2.9%	1.6%	2.4%	2.1%

Source: Eurostat (2021h), own calculations and illustration

To compare the demand for professional care and potential reasons for disuse, the following table presents the use of professional care divided by income groups and the degree of urbanization. The income is measured concerning the poverty line and given in under 60 % of median equivalised income and over 60 % of median equivalised income. For Romania, there is only limited data available. The comparison in Table 45 shows that in the Netherlands, a high rate of people under 60 % of median income receives professional care at home (5.0 % in cities, 7.3 % in suburbian and 6.9 % in rural areas). In contrast, at over 60 % of median equivalized income, the rate is higher in cities (5.7%). The same occurs for Switzerland (2.5 % vs. 2.9 % over 60 % of median income in cities, but 2.0 % vs. 1.6 % in the suburbs and 3.3 % vs. 2.2 % in rural areas). In Italy, the use of professional care is higher when there is higher income, especially in cities (0.6 % vs. 1.4 %).

Table 45: Individuals receiving professional home care by income group and degree of urbanization, 2016

Income	Countries	Cities	Towns & suburbs	Rural	Total
under 60% of median equivalized income	Italy	0.6%	1.0%	1.2%	0.9%
under 60% of median equivalized income	Netherlands	5.0%	7.3%	6.9%	5.8%
under 60% of median equivalized income	Romania	n.a.	n.a.	n.a.	n.a.
under 60% of median equivalized income	Switzerland	2.5%	2.0%	3.3%	2.5%
over 60% of median equivalized income	Italy	1.4%	1.1%	1.4%	1.3%
over 60% of median equivalized income	Netherlands	5.7%	5.3%	5.3%	5.5%
over 60% of median equivalized income	Romania	0.2%	0.1%	0.3%	0.2%
over 60% of median equivalized income	Switzerland	2.9%	1.6%	2.2%	2.1%

Source: Eurostat (2021h), own calculations and illustration

Because of less demand for professional care, it can be interpreted that many dependents are not able to pay the care when having less income, and so informal care occurs. For more detailed information, the main reasons for the disuse of professional home care are stated. Especially in Romania, 70.1 % of people who are not receiving professional care declared that professional home care could not be used because of financial reasons. Compared to Italy, the share is 36.9 % and 30.3 % of people who did not receive professional home care also declared that there are no care services available. In the Netherlands, the main reasons are that there is no care needed (40.6 %) or 30.3 % because of financial resources. In Switzerland,

only 18.9 % indicated that financial reasons occur, while often there is no need (36.6 %) or other reasons (34.6 %) are given (see Table 46).

Table 46: Individuals not receiving professional home care by degree of urbanization and reason professional home care is not used, 2016

Urbanization	Financial reasons	No need	Unsatis-factory quality of the services available	Will be rejected by the person in need of this care	No care services available	Others
Italy: Cities	36.8%	15.5%	4.5%	1.8%	22.4%	18.9%
Italy: Towns & suburbs	34.1%	13.3%	4.9%	1.7%	38.9%	7.1%
Italy: Rural	41.1%	14.1%	2.0%	2.2%	29.5%	11.2%
Italy: Total	36.9%	14.3%	4.0%	1.9%	30.3%	12.6%
Netherlands: Cities	32.6%	37.6%	0.8%	2.0%	9.3%	17.8%
Netherlands: Towns & suburbs	26.5%	44.3%	0.8%	4.8%	7.6%	16.0%
Netherlands: Rural	30.2%	45.9%	0.4%	1.4%	5.1%	17.1%
Netherlands: Total	30.3%	40.6%	0.7%	2.9%	8.3%	17.1%
Romania: Cities	75.1%	15.4%	n.a.	3.2%	4.4%	1.9%
Romania: Towns & suburbs	44.8%	15.9%	n.a.	15.7%	23.7%	n.a.
Romania: Rural	74.5%	11.1%	n.a.	3.5%	7.2%	3.7%
Romania: Total	70.1%	12.8%	n.a.	5.3%	9.1%	2.7%
Switzerland: Cities	35.2%	32.0%	2.5%	4.3%	4.5%	21.5%
Switzerland: Towns & suburbs	9.6%	36.1%	1.4%	7.2%	1.6%	44.1%
Switzerland: Rural	10.1%	44.9%	0.8%	5.3%	0.9%	38.0%
Switzerland: Total	18.9%	36.6%	1.7%	5.7%	2.5%	34.6%

Source: Eurostat (2021i), own calculations and illustration

3.2. Informal Caregiving

This section analyses informal caregiving though records are limited to the four countries chosen. In Italy, 9 out of 10 informal caregivers are women. Approx. 14 % of mid-life working women in Italy reduced or gave up labor market participation due to caring family members (Il Sole 24 Ore, 2018:online; Jessoula et al. 2018:11). In addition, there are many migrant workers (around 700,000 migrant workers in 2008) for care activities (European Commission 2019a:394ff). In the Netherlands, the number of informal caregiving persons was 3,500,000 in 2008 and 18 % of the total population were informal caregivers in 2016. Thereby, women have a greater share of informal caregiving than men (about 10 %; Zigante, 2018:18f; European Commission, 2019:433). Whereas in Romania, half of the Dutch rate occurs, with only 9 % of the total population being informal carers in 2016 (Zigante 2018:18f). In Switzerland, mostly relatives care for family members, which is reported as unpaid (Federal Statistical Office

2018:online). Only in-kind benefits for family carers, such as information and training opportunities, are available (Trein 2018:9; see Table 47).

Table 47: Informal caregivers, 2016/2017

Countries	18 to 34 years	35 to 64 years	65 years and above	18 to 64 sears (working age)	Work and care
Italy	12.0%	20.0%	18.0%	10.5%	5.8%
Netherlands	10.0%	23.0%	17.0%	9.3%	6.3%
Romania	5.0%	11.0%	9.0%	16.1%	10.4%
Switzerland	33.5%	36.5%	36.1%	29.7%	35.1%

Source: Zigante 2018:18f, Federal Office of Public Health 2018:online, Federal Statistical Office 2018:online, OECD 2019d:236

Table 48: Persons, 16 years and older providing informal care or assistance in 2016 distributed by hours per week and by men and women, 2016

Population and Countries	Less than 10 hours per week	10 to 19 hours per week	20 and more hours per week
Men: Italy	43.0%	20.4%	36.6%
Men: Netherlands	88.8%	7.9%	3.4%
Men: Romania	61.2%	23.3%	15.5%
Men: Switzerland	85.5%	11.2%	3.2%
Women: Italy	35.6%	21.6%	42.8%
Women: Netherlands	86.4%	10.4%	3.2%
Women: Romania	46.9%	29.9%	23.2%
Women: Switzerland	84.9%	10.4%	4.6%
Total: Italy	38.3%	21.2%	40.5%
Total: Netherlands	87.5%	9.2%	3.3%
Total: Romania	51.7%	27.7%	20.6%
Total: Switzerland	85.2%	10.8%	4.1%

Source: Eurostat (2021j), own calculations and illustration

Hours-worked by informal caregivers splits up into three time-lots ranging from less than 10 hours, 10 to 19 or 20 and more hours per week. On principle, the quota of informal caregivers is higher with fewer hours of care/assistance in all countries, except Italy. In Italy, the total rate of caregivers caring 20 or more hours (40.5 %) is higher than for those caring 10-19 hours (39.3 %) or even at less than 10 hours (39.3 %). The highest total rate of informal caregivers is present in the Netherlands (87.5 %) when it comes to providing care/assistance for less than 10 hours per week. As for men, the highest rate has Switzerland for less than 10 hours (85.5 %), for 10 to 19 hours in Romania (23.3 %) and for 20 and more hours in Italy (36.6 %). As for women, the Dutch have the highest quota for less than 10 hours (86.4 %), followed by Switzerland with the same span of hours (84.9 %). In the other time-lots, Romania has the highest value for 10 to 19 hours (29.9 %) and Italy for 20 and more hours (42.8 %). The lowest rate is shown in Switzerland within men (3.2 %) when it comes to care/assistance activities of 20 and more hours (see Table 48).

Table 49: Informal care or assistance givers by age groups and hours worked per week, 2016

Hours of care or	assistance activities Countries	16 to 24 years	25 to 34 years	35 to 44 years	45 to 54 years	55 to 64 years	65 to 74 years	75 years and above
Less than 10 hours per week	Italy	53.8%	46.7%	45.7%	39.9%	37.9%	32.4%	22.2%
Less than 10 hours per week	Netherlands	94.7%	94.2%	92.0%	92.2%	85.7%	75.8%	72.6%
Less than 10 hours per week	Romania	-%	61.3%	63.5%	41.8%	35.4%	39.4%	23.6%
Less than 10 hours per week	Switzerland	93.0%	89.6%	90.7%	87.9%	84.0%	82.1%	71.4%
10 to 19 hours per week	Italy	25.7%	24.5%	22.4%	23.2%	21.9%	19.2%	10.1%
10 to 19 hours per week	Netherlands	5.1%	4.3%	6.5%	6.4%	11.1%	16.4%	16.7%
10 to 19 hours per week	Romania	-%	19.6%	25.6%	44.3%	23.5%	34.7%	41.7%
10 to 19 hours per week	Switzerland	6.7%	9.4%	7.2%	9.7%	11.6%	13.2%	15.6%
20 and more Hours per week	Italy	20.5%	28.9%	31.9%	36.8%	40.2%	48.4%	67.7%
20 and more Hours per week	Netherlands	0.2%	1.5%	1.6%	1.5%	3.2%	7.8%	10.7%
20 and more Hours per week	Romania	-%	19.2%	10.9%	14.0%	41.1%	25.9%	34.7%
20 and more Hours per week	Switzerland	30.0%	1.0%	2.1%	2.4%	4.4%	4.7%	13.0%

Source: Eurostat (2021j), own calculations and illustration

For establishing a profile of caregivers, the age groups of informal caregivers and hours worked in the respective countries are analyzed, showing a great dispersion. The Netherlands has the highest number of informal caregivers in the age group from 16 to 24, providing less than 10 hours per week (94.7 %), succeeded by Switzerland within the same age group (93.0 %); there is no data available for the age group of 16 to 24 in Romania. It can be seen that in the first time-lot (less than 10 hours) the rates start high by the age group of 16 to 24 years in all countries and slightly decrease until the age group of 75 and older. The informal caregivers, who provide informal care from 10 to 19 hours per week have the highest rates in the age group of

from 45 to 54 in Italy (23.2 %) and Romania (44.3 %), in the Netherlands in the age group from 35 to 44 (6.5 %) and in Switzerland, the rates increase with the higher age (15.6 % at the age of 75 and older). Even with 20 hours and more, the rate of informal caregivers increases in Italy and the Netherlands with higher age (up to 67.7 % and 10.7 %). In Romania, there is a slight decrease at the age groups from 35 to 44 and then increases again. The same applies to Switzerland where 30.0 % of 16 to 24 olds are informal caregivers for 20 or more hours per week, but then the rate is quite low at the age group ranging from 25 to 35 years (1.0 %) and then slightly increases with increasing age. The lowest rate of informal caregivers is recorded in the Netherlands from 16 to 24 years, providing 20 or more hours (0.2 %). The level of the quotas also reflects the total number of informal caregivers in the age groups.

The distribution by the degree of urbanization shows care activities lasting less than 10 hours per week are almost the same in each degree of urbanization in all countries analyzed. Hours of care activities decrease with more hours of care in all areas, only in Italy the percentage of informal caregivers providing 20 and more hours is high in cities (40.4 %), suburbs (39.3 %), and rural (35.4 %) areas. The lowest percentage of informal caregivers is observed in rural areas of Switzerland (3.3 %), when it comes to 20 or more hours providing care. No general statement can be made regarding a significant distribution between cities, suburbs and rural areas, as the distribution varies roughly evenly depending on the hours and country (see Table 50).

Table 50: Informal care or assistance givers by degree of urbanization and hours worked per week, 2016

Urbanization	Countries	Less than 10 hours per week	10 to 19 hours per week	20 and more hours per week
Cities	Italy	39.8%	19.8%	40.4%
Cities	Netherlands	86.4%	10.1%	3.6%
Cities	Romania	52.1%	26.9%	21.1%
Cities	Switzerland	86.2%	9.3%	4.5%
Towns & suburbs	Italy	38.9%	21.7%	39.3%
Towns & suburbs	Netherlands	89.2%	8.1%	2.7%
Towns & suburbs	Romania	60.7%	22.4%	16.9%
Towns & suburbs	Switzerland	85.2%	11.0%	3.8%
Rural	Italy	42.5%	22.1%	35.4%
Rural	Netherlands	88.5%	8.9%	2.6%
Rural	Romania	61.4%	22.1%	16.5%
Rural	Switzerland	82.2%	14.4%	3.3%
Total	Italy	38.3%	21.2%%	40.5%
Total	Netherlands	87.5%	9.2%%	3.3%
Total	Romania	51.7%	27.7%	20.6%
Total	Switzerland	85.2%	10.8%	4.1%

Source: Eurostat (2021j), own calculations and illustration

In conclusion, Italy, the Netherlands and Romania provide direct payment for the dependent people, while in Switzerland there is an indirect payment, meaning the service is paid, but the dependents do not receive the money. As regards informal caregivers, the quota is mainly high when it comes to providing care for less than 10 hours per week. Only in Italy, the rate of informal caregivers is higher for 20 and more hours of caregiving (40.5 %). In all countries,

more female caregivers occur with more hours of care activity. When looking at age groups, there is no uniform pattern, and the rate of informal caregivers varies from country to country. The same applies to the subdivision of cities, suburbs and rural areas. To summarize, the rate of informal caregivers seems high in the Netherlands and Switzerland, but only below 10 hours of care activity. Over 10 hours, the number of informal caregivers is overall higher in Italy and Romania, reflecting statements from literature and the quota regarding formal home care. Professional home care is higher in the Netherlands and Switzerland than in the two other countries where the dependent persons' financial resources seem to be decisive.

3.3. Labour Force Participation

In 2019, the employment rate was the highest in Switzerland with 84.3 %, followed by the Netherlands with 80.9 %. In Romania (68.6 %) and Italy (65.7 %) the rates were at a comparably low level. Men have higher employment rates than women in all countries analyzed, with the highest discrepancies in Italy (18.5 percentage points) and Romania (19.1 percentage points; see Table 51).

Table 51: Employees and economically active persons by gender, 2019

Country and Sex	2019
Italy: Men	75.0%
Italy: Women	56.5%
Italy: Total	65.7%
Netherlands: Men	85.1%
Netherlands: Women	76.7%
Netherlands: Total	80.9%
Romania: Men	78.0%
Romania: Women	58.9%
Romania: Total	68.6%
Switzerland: Men	88.3%
Switzerland: Women	80.2%
Switzerland: Total	84.3%

Source: Eurostat (2021k), own calculations and illustration

The higher the educational attainment level, the higher the employment rate in all four countries analyzed. The highest rate at the primary educational level shows the Netherlands and Switzerland with 61.3 %. Almost the same applies to the secondary level, with Switzerland (80.3 %) and the Netherlands (80.2%) ranking at the top. Romania's tertiary educational level has the highest value (89.2 %), more than double compared to the primary level (44.4 %). Swiss men (92.6 %) on a tertiary level have the highest employment rate, followed by male Romanians (91.2 %) and the Dutch (90.8 %). Conversely, Italian women with primary education (30.2 %) succeeded by female Romanians (32.9 %) rank at the bottom. The lowest rate for men occurs in Italy with primary education (56.4 %), though it is 26.2 percentage points higher than the lowest employment rate for women with primary education (see Table 52)

Table 52: Employment rates by gender and highest educational attainment level (ISCED11), 2019

Country & Sex	Educational attainment level: Primary	Educational attainment level: Secondary	Educational attainment level: Tertiary
Italy: Men	56.4%	74.1%	83.3%
Italy: Women	30.2%	55.6%	75.7%
Italy: Total	44.0%	64.9%	78.9%
Netherlands: Men	68.7%	83.9%	90.8%
Netherlands: Women	53.6%	76.5%	86.5%
Netherlands: Total	61.3%	80.2%	88.6%
Romania: Men	56.8%	77.5%	91.2%
Romania: Women	32.9%	58.6%	87.3%
Romania: Total	44.4%	68.6%	89.2%
Switzerland: Men	66.1%	83.8%	92.6%
Switzerland: Women	56.5%	77.2%	84.7%
Switzerland: Total	61.3%	80.3%	89.0%

Source: Eurostat (2021l), own calculations and illustration

Analysis by the degree of urbanization in Romania reveals employment rate decreases from comparably high values in cities to low values in rural areas. The opposite occurs in the Netherlands and Switzerland, whereas there is almost no dispersion in Italian regions. Concerning differences by gender, the male employment rate increases from cities to rural areas, whereas female employment evolves in the opposite direction (in Italy). In the Netherlands and Switzerland, male and female employment rates increase from cities to rural areas. In Romania, male employment is highest in cities, followed by rural areas and lowest in cities and suburbs. In contrast, women's employment decreases from cities to less densely populated areas (see Table 53.).

Table 53: Employment rates by gender and degree of urbanization, 2019

Country & Sex	Cities	Towns & suburbs	Rural
Italy: Men	66.6%	68.9%	68.4%
Italy: Women	52.7%	49.4%	47.9%
Italy: Total	59.5%	59.1%	58.2%
Netherlands: Men	80.3%	84.6%	85.9%
Netherlands: Women	72.7%	75.8%	76.7%
Netherlands: Total	76.5%	80.2%	81.4%
Romania: Men	76.4%	73.2%	74.1%
Romania: Women	64.5%	52.9%	52.3%
Romania: Total	70.2%	63.1%	63.9%
Switzerland: Men	82.9%	84.7%	86.6%
Switzerland: Women	75.5%	76.0%	78.6%
Switzerland: Total	79.3%	80.4%	82.7%

Source: Eurostat (2021m), own calculations and illustration

Working part-time is often caused by care or assistance responsibilities, and the following table focuses on this part-time work (as a percentage of total employment). The Netherlands has both the highest rate of part-time workers in total (50.2 %) and also for women (75.2 %). Romania has the lowest rates (6.1 % in total and 6.0 % for men). Generally speaking, women are more likely to work part-time than men. Except for Romania, this gap is striking, ranging from 24.7 percentage points in Italy to 44.6 and 47.3 percentage points in Switzerland and the Netherlands (see Table 54).

Table 54: Part-time employment as a percentage of total employment by gender, 2019

Country	Total	Men	Women
Italy	18.7%	8.2%	32.9%
Netherlands	50.2%	27.9%	75.2%
Romania	6.1%	6.0%	6.2%
Switzerland	38.0%	17.1%	61.7%

Source: Eurostat (2021n), own calculations and illustration

Concluding, labor force participation is the highest in Switzerland and lowest in Italy, and the same result applies to the employment rate. Noteworthy is that women's labor force participation is lower than the men's in all counties. Moreover, the share of part-time working women is higher than the men probably relying upon traditional structures. Remarkable is the employment of women living in rural areas is higher than those living in cities in Switzerland and the Netherlands. Concerning care responsibilities, this is maybe because of higher care provision offered by professional services in the Netherlands and Switzerland, and women are therefore not/less bound to care responsibilities.

3.4. Voluntary work

Voluntary work splits up between formal, i.e. activities within an organizational context (clubs, groups, organizations), and informal activities, i.e. unpaid work undertaken by personal initiative without any institutional framework. The following parts of formal and informal volunteering include active citizenship, contact with family and friends, seeking help or face-to-face discussions and communication via social media. Active participation in cultural and social life is linked to individual lifestyles and cultural and social habits. Romania has the lowest participation rates in volunteering. In comparison to other member states of the EU, Romania has one of the lowest rates (only 3.2 %). The differences are attributed to the states' different cultural and social interests, as well as historical reasons. However, considering the differences between men and women, they are only minor. In Italy and Romania, women participate more in both formal and informal voluntary activities (12.1 % and 3.6 %), in the Netherlands, women participate more in formal (40.8 %) and men more in informal (84.8 %) volunteering. Men are also more formally active (39.3 %) in Switzerland, while women have a higher share in informal voluntary activities (52.3 %). As for active citizenship in all countries, more men than women participate (see Table 55).

Table 55: Participation in formal and informal activities or active citizenship of total population by gender, 2015

Country & Sex	Formal voluntary activities	Informal voluntary activities	Active citizenship
Italy: Men	11.8%	10.4%	6.8%
Italy: Women	12.1%	11.9%	5.7%
Italy: Total	12.0%	11.2%	6.3%
Netherlands: Men	39.7%	84.8%	25.7%
Netherlands: Women	40.8%	80.3%	24.9%
Netherlands: Total	40.3%	82.5%	25.3%
Romania: Men	2.9%	2.8%	3.9%
Romania: Women	3.4%	3.6%	3.3%
Romania: Total	3.2%	3.2%	3.6%
Switzerland: Men	39.3%	43.9%	29.8%
Switzerland: Women	33.7%	52.3%	24.1%
Switzerland: Total	36.5%	48.2%	26.9%

Source: Eurostat (2021o), own calculations and illustration

Participation rates within age groups differ slightly in the countries analyzed. In Italy, the Netherlands, and Romania, the rate decreases with higher age. In Switzerland, participation increases regarding informal volunteering until the age group of 65 to 75 years and then decreases (from 58.2 % to 44.1 % in the age group 75 years and above). In the Netherlands and Switzerland, informal voluntary work is more present than formal, whereas in Romania and Italy, respective values are almost equal (except for Italy in the age group 16 to 24 years; see Table 56).

Table 56: Participation in formal or informal voluntary activities by age groups, 2015

Countries	Age groups	Formal voluntary activities	Informal voluntary activities
Italy	16 to 24 years	16.2%	11.8%
Italy	24 to 64 years	12.6%	12.1%
Italy	65 to 75 years	11.4%	11.3%
Italy	75 years and above	5.9%	5.7%
Netherlands	16 to 24 years	45.5%	90.2%
Netherlands	24 to 64 years	42.2%	86.6%
Netherlands	65 to 75 years	38.7%	77.3%
Netherlands	75 years and above	20.1%	47.2%
Romania	16 to 24 years	8.3%	7.4%
Romania	24 to 64 years	2.9%	3.1%
Romania	65 to 75 years	1.6%	1.7%
Romania	75 years and above	0.8%	0.6%
Switzerland	16 to 24 years	39.3%	44.2%
Switzerland	24 to 64 years	37.9%	47.6%
Switzerland	65 to 75 years	35.6%	58.2%
Switzerland	75 years and above	22.7%	44.1%

Source: Eurostat (2021p), own calculations and illustration

In 2015, the counties' participation, divided into cities, suburbs, and rural areas, shows that the highest rate of voluntary formal involvement is in the rural area of the Netherlands (44.9 %) where also the informal voluntary activities are highest (84.3 %). Furthermore, participation in active citizenship is highest in Swiss (28.4 %) and Dutch cities (27.2 %). On the contrary, the lowest rate for active citizenship occurs in rural areas of Romania (2.3 %). Additionally, the participation rates for all voluntary activities are lowest in rural areas in Romania (2.1 % and 1.6 %). Regarding Italy, participation rates are lower than in the Netherlands or Switzerland, but they are almost the same for all degrees of urbanization (see Table 57).

Table 57: Participation in formal and informal activities or active citizenship by degree of urbanization, 2015

Countries	Urbanization	Formal voluntary activities	Informal voluntary activities	Active citizenship
Italy	Cities	11.4%	11.8%	6.8%
Italy	Suburbs	12.3%	10.8%	6.0%
Italy	Rural	12.2%	10.9%	5.9%
Netherlands	Cities	36.1%	82.4%	27.2%
Netherlands	Suburbs	43.1%	81.6%	23.4%
Netherlands	Rural	44.9%	84.3%	23.8%
Romania	Cities	3.2%	3.8%	4.0%
Romania	Suburbs	5.1%	5.2%	5.6%
Romania	Rural	2.1%	1.6%	2.3%
Switzerland	Cities	29.7%	45.2%	28.4%
Switzerland	Suburbs	36.2%	47.9%	25.8%
Switzerland	Rural	44.2%	52.0%	27.1%

Source: Eurostat (2021q), own calculations and illustration

Table 58: Participation in formal and informal activities or active citizenship by educational attainment level (ISCED 2011), 2015

Countries	Educational level	Formal voluntary activities	Informal voluntary activities	Active citizenship
Italy	Primary	8.4%	8.0%	3.5%
Italy	Secondary	8.4%	12.6%	7.5%
Italy	Tertiary	14.6%	17.1%	11.7%
Netherlands	Primary	29.7%	69.2%	12.5%
Netherlands	Secondary	39.1%	84.6%	24.2%
Netherlands	Tertiary	49.7%	89.7%	36.3%
Romania	Primary	2.1%	1.6%	2.0%
Romania	Secondary	2.7%	3.2%	3.5%
Romania	Tertiary	8.2%	8.2%	9.3%
Switzerland	Primary	24.9%	41.1%	15.6%
Switzerland	Secondary	36.7%	50.3%	25.7%
Switzerland	Tertiary	42.9%	48.7%	35.6%

Source: Eurostat (2021p), own calculations and illustration

The higher the educational attainment level, the higher the voluntary participation rates for all countries analyzed. The highest participation rate for formal (49.7 %) and informal voluntary work (89.7 %), as well as active citizenship (36.3 %), occurs on tertiary educational attainment level (49.7 %) in the Netherlands (see Table 58).

Summing up, the extent of voluntary work varies a lot in the countries analyzed: Participation in voluntary work in Romania is quite low compared to Switzerland (3.2 % vs 36.5 % in formal volunteering). Voluntary work is somewhat more frequent in Italy but the Swiss and Dutch (12.0 % vs. 36.3 % and 40.3 % in formal voluntary work) have rates twice as high. Volunteering disperses with aging as rates are lower for comparably old groups. However, striking is that the higher the educational attainment level is, the higher the rates of volunteering and active citizenship are. Furthermore, participation might also correlate with income, as higher educational levels yield higher wages.

4. *Exemplary evaluation of the non-reactive indicators of Smart VitAALity*

Within the framework of this comprehensive analysis, non-reactive indicators of a specific AAL technology are determined exemplarily in all four countries, i.e. Italy, the Netherlands, Romania and Switzerland. In order to justify the choice of the technology, the application areas of developed AAL solutions (of the European AAL Programme countries) were analyzed in the respective countries. In all four countries, the areas "Health & Care", "Information & Communication" and "Vitality & Abilities" are most relevant (Call 1 to Call 2020; see Table 59).

Table 59: AAL Programme by application areas (multiple categorization), Call 1 to Call 2020

Application Areas	Italy	Netherlands	Romania	Switzerland	All AAL Programme Countries
Health & Care	21.8%	20.9%	23.1%	21.2%	**21.5%**
Information & Communication	26.4%	25.5%	19.6%	21.5%	**25.1%**
Leisure & Culture	8.6%	9.5%	6.5%	5.5%	**7.8%**
Livings & Buildings	5.1%	3.0%	4.0%	5.2%	**3.5%**
Mobility & Transport	6.1%	6.8%	5.0%	6.2%	**6.6%**
Safety & Security	9.6%	7.2%	8.0%	7.8%	**7.8%**
Vitality & Abilities	11.7%	13.3%	15.6%	15.6%	**14.5%**
Work & Training	6.6%	9.1%	13.1%	11.1%	**8.7%**
Body Functions	4.1%	4.6%	5.0%	5.9%	**4.5%**
Total	**100.0%**	**100.0%**	**100.0%**	**100.0%**	**100.0%**

Source: AAL Programme (2021), own calculations and illustration

For this reason, the non-reactive indicators of Smart VitAALity are determined in the selected four countries, because Smart VitAALity also has a focus on "Health & Care" and "Vitality & Abilities"; only in "Safety & Security" and "Information & Communication" is there a deviation. However, in the project description of Smart VitAALity it is also described that the usage competence of older persons in dealing with information and communication media is to be increased, which is in line with the application area "Information & Communication" and therefore the discrepancy is negligible.

In terms of methodology, the socio-economic potential analysis of Smart VitAALity focused on the selection of the relevant parameters for the cost-benefit analysis (CBA) and cost-utility analysis (CUA). Subsequently, data research and interviews with primary users (reactive data collection methods) were conducted to determine the relevant data. Based on this, the costs and the benefits or the utility value could be calculated. Discounting and sensitivity analysis also play a role in determining the result so that these can be comprehensively assessed. The details of the analysis are described in the following paragraphs.

The parameters to be included in the CBA, as well as the CUA, were obtained based on existing relevant literature dealing with health economic evaluation of telehealth/-medicine technologies. The validation of these parameters occurred in workshops of the Smart VitAALity project consortium. The choice of parameters was limited to the effects for the primary and tertiary stakeholders, i.e. the benefits and costs for the users of the technical assistance system as well as the financiers. Table 60 provides an overview of the cost and benefit parameters selected for the respective analyses. With regard to the determination of costs, the relevant direct and tangible costs, i.e. costs that can be measured in monetary terms, were used in the analysis by Aigner-Walder/Luger/Ofner (2020). These can basically be divided into intervention costs (equipment, operation, support and care center), medical costs (doctor visits, outpatient visits and hospital stays) and non-medical costs (use of mobile care and support services, rescue and ambulance transport). Quality-adjusted life years (QALYs) were calculated for the CUA. These are composed of two factors quality of life and life expectancy. In this respect, intangible benefit parameters were taken into account in the course of the CUA by applying a standardized measure of health-related quality of life developed by the EuroQol, i.e. EQ-5D-5L questionnaire (reactive data).

Table 61 shows the costs of the Smart VitAALity system split up into the categories "Software & Services" and "Hardware". Hardware components are electronic devices like tablets, scales, blood glucose meters, blood pressure meters, a data hub, and a smartwatch. These components are available from specialist retailers. “Software & Services" include mobile security, an emergency call center, a health monitoring system, and a Sim card required for data transmission. The following lists and tables discuss the software and hardware prices for direct sales to end customers. The implementation of Smart VitAALity took place in Austria. Consequently, Austrian prices serve as the basis for transnational pre-testing of non-reactive indicators. In this regard, differing situations regarding income and spending must be taken into account, i.e., purchasing powers parities (PPP).

Table 60: Selected cost and benefit parameters of health economic evaluation of Smart VitAALity

Costs and benefits/ utilitues	Details	Cost-Benefit Analysis (CBA)		Cost-Utility Analysis (CUA)	
Intervention Costs	Equipment (e.g., tablet, smartwatch, installation)	X		X	
Intervention Costs	Operation (e.g., Internet costs, electricity costs)	X		X	
Intervention Costs	Support (e.g., employees, maintenance)	X		X	
Intervention Costs	Care Center (e.g., employees, material costs)	X		X	
Medical Costs	Physician visits (general practitioners, internists)	X		X	
Medical Costs	Outpatient visits	X		X	
Medical Costs	Hospital visits	X		X	
Non-medical Costs	Usage of mobile nursing and care services	X		X	
Non-medical Costs	Rescue and ambulance services	X		X	
Relief for users and relatives	Relief for users (e.g., savings on physician visits)		X		
Relief for users and relatives	Relief of informal care & nursing (e.g., time savings)		X		
QALY	Quality of life				X
QALY	Life expectancy				X

Source: Aigner-Walder/Luger/Ofner (2020; own illustration)

Purchasing power parities (PPPs) are indicators of price level differences between countries. They indicate how many currency units a given quantity of goods and services costs in different countries. As the realization of Smart VitAALity took place in Austria, prices of the reporting country serve as a reference. PPPs can thus be used as currency conversion rates to convert expenditures expressed in national currency into a common artificial currency (the purchasing power standard, PPS), thus eliminating the effect of price level differences between countries. Purchasing power parity is also used as an economic indicator of economic convergence between different economies. The prices used for Austria in the table above are those for the hardware and software and service components communicated by the provider during the project; these are retail prices in the case of direct sales.

The prices for Italy, the Netherlands, Romania and Switzerland were weighted according to the respective purchasing power in product groups (e.g. product group "A010901 Audio-visual, photographic and information processing equipment" according to OECD & Eurostat (2012)) and must be understood as a benchmark for purchasing power in Austria.

Hardware refers to so-called tradable goods, i.e. in most cases, physical products such as tablets or smartwatches can be traded internationally. Therefore, these goods have the same or a comparable absolute price in the different countries, apart from transport costs and in the absence of trade barriers. The prices of tradable goods are determined by supply and demand on the world market, not by national circumstances. Against the background of differing income levels, it is striking with regard to hardware that Austria has the highest purchasing power for

almost all components. Italy has approx. the same purchasing power; about € 20 more has to be paid for comparable products. The Netherlands ranks behind with approx. additional cost of € 65. Switzerland is generally known for its high and, therefore attractive potential earnings. The fact that these high incomes are within this comparison not as high as they seem can be deduced from the higher price level of goods and services and the associated purchasing power parities. For comparable hardware components, the price in Switzerland is approx. € 210 more than in Austria. As expected, the greatest discrepancy is found in the emerging market of Romania, where the relative expenditure of approx. € 3,000 is four times higher than in Austria.

Table 61: Costs of Smart VitAALity components, Purchasing Power Parities (€ PPP)

Software & Services	Austria: Price (per unit)	Italy: Price (per unit)	Netherlads: Price (per unit)	Romania: Price (per unit)	Switzerland: Price (per unit)
Mobile Security (Smartwatch)	€ 178.80	€ 154.43	€ 186.17	€ 272.86	€ 326.17
Emergency call center	€ 108.00	€ 93.28	€ 112.45	€ 164.82	€ 197.01
Health monitoring (with Health Coach)	€ 540.00	€ 466.41	€ 562.27	€ 824.08	€ 985.07
Total (Software)	**€ 826.80**	**€ 808.04**	**€ 859.39**	**€ 932.92**	**€ 1,583.14**
Hardware	**Price**	**Price**	**Price**	**Price**	**Price**
Smartwatch	€ 249,00	€ 258.82	€ 275.10	€ 1,133.46	€ 291.05
Single-board computers (SBC)	€ 93,60	€ 97.29	€ 103.41	€ 426.07	€ 109.41
Blood pressure monitor	€ 54,60	€ 53.36	€ 56.75	€ 61.61	€ 104.55
Blood glucose monitor	€ 46,80	€ 45.74	€ 48.64	€ 52.81	€ 89.61
Scale	€ 59,28	€ 61.47	€ 60.33	€ 267.63	€ 81.75
Tablet computer	€ 230.00	€ 239.07	€ 254.11	€ 1,046.97	€ 268.85
Total (Hardware)	**€ 733.28**	**€ 755.75**	**€ 798.34**	**€ 2,988.55**	**€ 945.22**

Source: ilogs information logistics GmbH; Eurostat (2021r), own calculations and illustration

The range of prices in the "Software & Services" categories is comparatively limited. This is mainly due to the support provided by trained personnel such as qualified medical and nursing staff (e.g., nurses), physicians or specially trained staff (e.g., health coaches). These health and care services are considered as non-tradable goods in a more narrow sense. They are characterized, for example, by high transport and customs costs and often the training required to practice a particular profession is not recognized abroad. For this reason, the services offered are limited to a specific country or a few countries, so that there is no uniform international price (see also nostrification). Software and service costs in Austria, Italy and the Netherlands are similar in terms of level: Italy always has the lowest costs, followed by Austria and the Netherlands. However, due to the economic situation in Switzerland and Romania and the associated price levels, the expected costs there are approximately twice as high as in the other three countries.

In contrast to CUA, where the utility values are recorded by standardized questionnaires (e.g. EQ-5D-5L; reactive method of data collection amongst primary users), the determination of benefits in CBA is done in monetary units. Treatment costs (e.g., by the general physician) are in most cases presented as a financial cost. Potential savings from reduced use of health and long-term care services as a result of using an age-appropriate assisting system represent a potential benefit. However, a potential outcome could also be increased utilization of such services, e.g., as a result of technology-induced misdiagnosis. An alternative non-reactive method for determining the utilization of services is the anonymized query of the patient's service information for the duration of the field test phase. Whether and to what extent such a query is permissible must be clarified with regard to the applicable legal (especially data protection) and ethical circumstances before the start of the project testing.

The recording of the selected parameters for the CBA is performed first in natural units (e.g. number of consultations of the physician), which were collected in the questionnaire survey before and at the end of the intervention in the households of the intervention and control group or via non-reactive procedures (e.g., accounting for service between the provider and the social insurance agencies). In the next step, the parameters are quantified on the basis of secondary statistical information provided by the respective national institutions or in the case of the table below by the World Health Organization. The data below is expressed as costs per unit (PPP I$ purchasing power parities) suitable for international comparison. As can be seen below, the rates for medical health services differ considerably. In this respect, it is important to take into account the different structures of the medical and nursing care systems, as described above. Prices of outpatient services in Austria and the Netherlands are at about the same level, compared to Italy, ranging slightly below, and Switzerland, slightly above. Romania ranks way below as prices per unit are approx. half of Italian. In terms of inpatient care expressed as cost per bed day (differentiated by primary, secondary and tertiary hospitals) almost the same costs apply to Austria, the Netherlands and Italy, as well as Romania and Switzerland having the lowest and highest prices again. However, the wide range of expenditures in the various categories of the analysis must once more be analyzed and interpreted in the context of the respective income level and the associated purchasing power (see Table 62).

Table 62: Costs of Health and Care Services, Purchasing Power Parities (€ PPP), 2010

Outpatient visits (mean value from sample)	Austria: Price (per unit)	Italy: Price (per unit)	Netherlads: Price (per unit)	Romania: Price (per unit)	Switzerland: Price (per unit)
Health Centre (no beds)	I$ 47.57	I$ 37.84	I$ 48.26	I$ 18.98	I$ 54.76
Health Centre (with beds)	I$ 57.82	I$ 49.14	I$ 59.01	I$ 23.65	I$ 68.83
Primary Hospital	I$ 65.35	I$ 37.84	I$ 48.26	I$ 18.98	I$ 54.76
Secondary Hospital	I$ 67.56	I$ 54.13	I$ 71.24	I$ 28.83	I$ 79.39
Tertiary Hospital	I$ 67.23	I$ 56.10	I$ 70.04	I$ 29.24	I$ 81.07
Cost per inpatient bed day by hospital (without drugs; mean value from sample)	**Austria: Price (per unit)**	**Italy: Price (per unit)**	**Netherlads: Price (per unit)**	**Romania: Price (per unit)**	**Switzerland: Price (per unit)**
Primary Hospital	I$ 669.20	I$ 523.50	I$ 721.94	I$ 202.22	I$ 846.91
Secondary Hospital	I$ 704.05	I$ 531.64	I$ 732.47	I$ 210.68	I$ 885.00
Tertiary Hospital	I$ 933.49	I$ 700.95	I$ 945.65	I$ 272.20	I$ 1,144.88

Source: World Health Organization (2021); Stenberg et al. (2018); own calculations and illustration

In addition, providers' healthcare expenditures are analyzed, where a distinction is made between hospitals, residential long-term care facilities, providers of ambulatory health care, etc. The following table shows the different categories of health care expenditure by the provider. At the same time, the total costs (i.e., all providers of health care) are put in relation to the gross domestic product so that one gets an impression of how much these costs account for in relation to the national economic output of a calendar year. Taking into account both purchasing power (4,984.17 PPS) and economic output (11.15 %), these costs are the highest in Switzerland. As expected, the situation is the opposite in Romania (1,188.74 PPS and 5.56%). Austria, the Netherlands and Italy are repeatedly at a similarly high level.

Table 63: Health care expenditure by provider (€ PPS per inhabitant), 2018

Country	Austria	Italy	Netherlands	Romania	Switzerland
Hospitals	€ 1,525.97	€ 1,108.71	€ 1,337.93	€ 552.66	€ 1,830.04
Residential long-term care facilities	€ 341.01	€ 157.77	€ 1,077.34	€ 21.61	€ 832.59
Providers of ambulatory health care	€ 909.54	€ 589.24	€ 722.56	€ 176.84	€ 1,318.94
Providers of ancillary services	€ 117.79	€ 110.92	€ 61.34	€ 69.46	€ 109.52
Retailers and other providers of medical goods	€ 619.96	€ 416.61	€ 428.35	€ 298.39	€ 456.15
Providers of preventive care	€ 29.93	€ 89.65	€ 88.49	€ 3.27	€ 68.19
Providers of health care system administration and financing	€ 158.10	€ 40.91	€ 167.36	€ 34.91	€ 260.89
Rest of economy	€ 227.27	€ 0.00	€ 43.41	€ 18.92	€ 65.71
Rest of the world	€ 30.87	€ 1.88	€ 28.94	€ 11.42	€ 42.14
Providers unknown	n.a.	€ 0.00	n.a.	€ 1.27	n.a.
All providers of health care	**€ 3,960.41**	**€ 2,515.69**	**3,955.65**	**1,188.74**	**4,984.17**
All providers ofhealth care (% of GDP)	**10.32%**	**8.68%**	**10.03%**	**5.56%**	**11.15%**

Source: Eurostat (2021s), own calculations and illustration

No statement can be made about the effectiveness and benefits, as Smart VitAALity had no significant effects in terms of savings (CBA) and quality of life (CUA). Although isolated indications were found that Smart VitAALity had a positive impact on individual quality of life dimensions by comparing results of respective dimensions at the beginning and the end of the intervention in intervention and control groups, these were only weakly significant and no overall improvement was found. But this analysis shows the high relevance of the consideration of the specific situation of economic and health structures and conditions for multinational comparisons.

From a multinational perspective, no conclusions can be drawn regarding the quality of life and effectiveness, as only non-reactive instruments were tested in advance. From an economic perspective, however, it can be assumed that more developed countries are more likely to benefit from such products and services since the hardware costs are comparatively low, but the wage level and the associated service costs in the health and care sector are high. Potential savings would therefore be realized, especially in these countries. However, the actual beneficiaries will depend on the design of the respective publicly financed health and care system. As the analysis of the 14 European countries of the AAL Programme has shown, these are designed very differently, and therefore many different stakeholders are involved in a decision-making process and they also differ in respect to market power.

In particular, the in-depth analysis for Italy, the Netherlands, Romania, and Switzerland shows that the competencies and tasks are divided differently between the national, federal, and municipal levels in all countries. In addition to the political level, however, the sectoral perspective must also be taken into account: Some services are not financed or not fully financed by the public system and therefore have to be covered by co-payments (or premium-financed private insurances). This results in a stakeholder problem in many respects, all of whom would benefit or even lose from such new technologies to different degrees and would therefore have different incentives.

For example, assuming AAL products and solutions reduce long-term care home beds. This would be a desirable state of affairs from a holistic and long-term public perspective. However, from a short-term regional perspective (at the municipal level), this would be associated with a loss of jobs (in the form of fewer nursing staff) and thus direct losses in the form of lost communal taxes in many countries. Indirectly, from a short-term regional economic perspective, further losses (e.g., lower regional value-added) would be associated with such a transition process. Therefore, it is questionable how cooperative municipalities, federal states, and the government would be in a nationwide implementation, as they each pursue their own goals and try to maximize their own benefits. In order to mediate between the parties involved, it is advisable to quantify the effects mentioned at the respective level and thus possibly contribute to a solution of the conflict.

Outlook

In EvAALuation[2] and 3vAAluation, an important step was taken to put the EvAALuation indicator set into practice, whereby future evaluations of AAL technologies are expected to be facilitated. We developed concrete data collection methods and measuring instruments to gather and assess data on a subjective, institutional, and societal level for the areas of health, care & support as well as being active & human potential. For reactive data, we developed question and answer items for standardized surveys. In the area of non-reactive methods, concrete survey instructions were established. In addition, we provide instructions on how to use the instruments, notes on how to avoid process errors, and data evaluation notes. Furthermore, we developed instructions for international studies including, among other things, an analysis of the publicly financed health and care system. We highlighted national differences in terms of health & care provision, financing & reimbursements, data protection & ethical issues as well as health technology assessment. An in-depth analysis and a pretest for cross-national evaluations were performed for Italy, the Netherlands, and Switzerland.

The application areas of health, care & support as well as being active & human potential that have been presented, are supposed to show the spectrum of existing AAL solutions and their impact potential, which have a strong tradition of research and development and will continue to be important. The limitation was necessary because not all of the indicators developed in EvAALuation are relevant for all AAL solutions (e.g., care and support services used), but also because concrete definitions of the indicators differ in part depending on the context and the associated intended effects (e.g. autonomy & self-determination). Nevertheless, the areas of application are only a selection of possible application contexts. Thus, future research activities should develop instruments for other important application areas such as housing, residential environment & public space or transport & mobility (see “AAL Vision” 2025 by Bertel et al. 2018).

In addition to this variety of AAL solution approaches, the diversity of older people must also be taken into account. The instruments developed only address the heterogeneity within the group of elderly people beyond the goals of the AAL products or services to a limited extent. Older people have different living environments, habits, and requirements, which must also be reflected in study designs. Therefore, the existing approaches need to be critically reviewed and subsequent projects need to develop adaptations for specific user groups, e.g. for people living with dementia, and to check whether the operationalizations account for relevant effects for people with different social identities, e.g. on the basis of gender, social class or race. The results presented in this manual are deliberately intended as a proposal that is open to extension and improvement.

To further facilitate evaluations, the development of a dashboard tool should be pursued. Such a tool could be used to select indicators interactively and intuitively and to generate instructions and manuals based on the respective indicators, including questionnaires and survey instructions. A semi-automated analysis could facilitate evaluations for persons who have less knowledge of statistics. Furthermore, an international benchmarking system based on real evaluations that are anonymized could be built.

From a multinational perspective, no conclusions can be drawn regarding the quality of life and effectiveness, as only non-reactive instruments were tested in advance. From an economic perspective, however, it can be assumed that more developed countries are more likely to benefit from AAL products and services since the hardware costs are comparatively low, but the wage level and the associated service costs are high. Potential savings would therefore be realized, especially in these countries. However, the actual beneficiaries will depend on the design of the respective publicly financed health and care system. As the overview analysis of the 14 European countries of the AAL Programme has shown, these are designed very differently, and therefore many different stakeholders are involved in decision-making processes (e.g. national, federal, municipal, social insurance).

In order to mediate between the parties involved, it is advisable to identify and quantify economic and social push and pull factors mentioned at the respective level and thus possibly contribute to a solution of the conflict. Building upon this, a framework for quantifying factors (e.g., potential savings and losses at the respective level) for implementation decisions and a guide for AAL implementation could subsequently be developed. Operationally, this could be accomplished, for example, by developing an econometric model to support strategic national and regional health and care planning.

As already stated in the handbook on the EvAALuation indicator set and EvAALuation^2 manual, it must also be noted at this point that the AAL field is subject to strong dynamics, and thus neither an indicator set nor the associated instruments can be regarded as complete. The present instruments can serve as a starting point for the development of further approaches to gather these innovations and additional impact dimensions.

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